

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 4/30/2020 5:24:59 PM
To: Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]
Subject: RE: Gilead and ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

Excellent

From: Lane, Cliff (NIH/NIAID) [E] [b6]
Sent: Thursday, April 30, 2020 12:51 PM
To: Wholley, David (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]
Cc: Tabak, Lawrence (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]
Subject: Gilead and ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

I received an email yesterday (prior to the press release) from a relatively senior scientist that Gilead has re-considered and would like to be part of ACTIV. I was going to mention it on the call this afternoon. I think having them as part of ACTIV – given they have a strong track-record and likely the first directly acting anti-viral - would be good.

Cliff

From: "Wholley, David (FNIH) [T]" [b6]
Date: Thursday, April 30, 2020 at 10:18 AM
To: "Collins, Francis (NIH/OD) [E]" [b6]; "Lane, Cliff (NIH/NIAID) [E]" [b6]
Subject: FW: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

FYI, something to think about.

From: Bozzette, Sam (NIH/NCATS) [E] [b6]
Sent: Thursday, April 30, 2020 9:19 AM
To: Adam, Stacey (FNIH) [T] [b6]; Butterson, Joan [b6]; Collins, Sylva (FDA/CDER) [b6]; Judy Currier [b6]; De Claro, R. Angelo (FDA/CDER) [b6]; Mark Eisner [b6]; Keith Gottesdiener [b6]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Elliott Levy [b6]; Sandeep Menon [b6]; Amanda Peppercorn [b6]; Proschan, Michael (NIH/NIAID) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Amanda Peppercorn [b6]; Price, Dionne (FDA/CDER) [b6]; Rubin, Daniel B. (FDA/CDER) [b6]; Shen, Yuan Li (FDA/CDER) [b6]; Farley, John (FDA/CDER) [b6]; Goff, David (NIH/NHLBI) [E] [b6]; Vincent, Michael [b6]
Cc: Mary Biggs [b6]; Demarcus [b6]; Macone, Erin [b6]; Tountas, Karen (FNIH) [T] [b6]; Wachtel, Jonathan [b6]; Elizabeth Kim [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Butcher, Tina [b6]; Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Wung, Peter /US [b6]; Qashu, Felicia (NIH/OD) [E] [b6]

COLL0000010854

b6

Stratton, Benjamin <bstratton@DELOITTE.com>

Subject: Re: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

Good morning all:

It would seem that our active control arm had been identified. Should we get in the queue with Gilead sooner rather than later - or have we already reached out to them?

S

From: "Adam, Stacey (FNIH) [T]"

b6

Date: Thursday, April 23, 2020 at 8:31:00 PM

To: "Bozzette, Sam (NIH/NCATS) [E]"

b6

"Butterton, Joan"

b6

"Collins, Sylva (FDA/CDER)"

b6

"Judy Carrier"

b6

"De Claro, R.

Angelo (FDA/CDER)"

b6

"Mark Eisner"

b6

"Keith Gottesdiener"

b6

"Eric Hughes"

b6

"LaVange, Lisa M"

b6

"Elliott Levy"

b6

"Sandeep Menon"

b6

"Amanda Peppercorn"

b6

"Proschan, Michael (NIH/NIAID) [E]"

b6

"Read, Sarah (NIH/NIAID) [E]"

b6

"Amanda Peppercorn"

b6

"Price, Dionne (FDA/CDER)"

b6

"Rubin, Daniel B.

(FDA/CDER)"

b6

"Shen, Yuan Li (FDA/CDER)"

b6

"Farley, John

(FDA/CDER)"

"Goff, David (NIH/NHLBI) [E]"

b6

"Vincent, Michael"

b6

Cc: "Mary Biggs" <

b6

"Demarcus"

b6

"Macone, Erin"

b6

"Tountas, Karen (FNIH) [T]"

b6

"Wachtel, Jonathan"

b6

"Elizabeth Kim"

b6

"Parker, Ashley (NIH/OD) [E]"

b6

"Butcher, Tina"

b6

"Wholley, David (FNIH) [T]"

b6

"Melencio, Cheryl (FNIH) [T]"

b6

"Wung, Peter /US"

b6

"Qashu, Felicia (NIH/OD) [E]"

b6

"Stratton, Benjamin"

Subject: RE: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

Dear TX-Clinical Master Protocol Subgroup,

Please find attached the materials for tomorrow's meeting.

1. Agenda
2. Slides for discussion updated with the decisions from today
3. A useful resource about current standard clinical treatment guidelines from the front lines for COVID. This may be a useful resource in selecting how to do minimal data collection and trying to understand SOC.

Please let me know if you have questions or other things you think would be helpful for the group to review.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

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b6

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b6

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Sent: 4/30/2020 10:17:45 PM
To: Srinivasan, Badhri [b6]; Vincent, Mike [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Bascles, Lionel [b6]; Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [b6]; Desrosiers, Betsy [b6]; Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshov, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshovj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; King, James (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce1f3853e43d4463a04f7d74992f96ac-James.King.]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura [b6]; Wachtel, Jonathan [jwachtel@deloitte.com]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]
CC: Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Garner, Carlos [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [b6]; Jansen, Kathrin [b6]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [b6]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [marganderson@deloitte.com]; Carluccio, Dana [b6]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny [b6]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [b6]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a27ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveson, Nancy [b6]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Criffield, Robin [b6]; Hamilton, Nancy [b6]; Minnich, Beth [b6]; Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Stratton, Benjamin [bstratton@DELOITTE.com]; Tolman, Brett [btolman@deloitte.com]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Jintanat Ananworanich [b6]

Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting
Attachments: Clinical Trial Capacity Working Group Meeting Agenda_05012020.pdf

Location: [b6]

Start: 5/1/2020 1:00:00 PM
End: 5/1/2020 2:00:00 PM
Show Time As: Tentative

Recurrence: Weekly
every Tuesday and Friday from 9:00 AM to 10:00 AM

Required Attendees: Srinivasan, Badhri; Vincent, Mike; Stein, Peter (FDA/CDER); Bascles, Lionel; Cohen, Myron; Corey, Larry; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshov, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; King, James; Kurilla, Mike; Nayak, Seema (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Payton, Manzone; Resnansky, Laura; Wachtel, Jonathan; Woodcock, Janet (FDA/CDER); Qashu, Felicia

Optional Attendees: Sizemore, Christine (NIH/FIC) [E]; Garner, Carlos; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Carluccio, Dana; Cheryl (FNIH) Melencio [T] [b6]; Francis Collins; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH); Tuveson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Minnich, Beth; Rebecca (NIH/NCATS) Katz [E] [b6]; Thomas, Ashley (FDA/CDER); Stratton, Benjamin; Tolman, Brett; Davey, Victoria; Jintanat Ananworanich

Dear Colleagues, Agenda is attached. During this call we will hear the latest from the three sub-WGs – innovations, inventory, and survey – which have been working very hard to move their activities forward quickly. Many thanks to all! We will also have a bit of a brainstorming session about creating a ‘dashboard’ to use in analyzing survey results. Best regards, Karen

ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines

Dear Clinical Trial Capacity Working Group members,

In anticipation of this working group making rapid progress on identified action items and other activities, the co-chairs have agreed that it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify areas of need, and to determine next steps. We ask that you make every effort possible to join each of these meetings, but understand that at times you may have competing priorities. To place a hold on your calendar, please accept this meeting invite with a response; later you can decline an individual meeting if you have a conflict.

An agenda and other meeting materials, as needed, will be distributed prior to each call.

With best regards,
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health

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CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bafd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: Follow-up Materials to ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting #5-Including New Score Sheet (Agents Added)
Attachments: lancet respiratory medicine.pdf; Immunohemostasis 2017 v032920.pdf; C19 Coagulopathy BLOOD 042720.pdf; Amgen - Otezla (Apremilast).pdf; Takeda - Takhzyro (Lanadelumab)- summary.pdf; Takeda - Firazyr (Icatibant) - summary.pdf; Lilly-Taltz.pdf; BMS - Orencia (Apatacept).pdf; Allergan - Cenicriviroc.pdf; EIDD-2801.pdf; Thromboinflammation Blood-2018-11-882993.full.pdf; Thromboinflammation JTH Ed 041720.pdf; cell research 2020.pdf; compound list caco cells.pdf; preprints202004.0149.v1.pdf; Riva2020_REFRAME drug repositioning against SARS-CoV-2.pdf; ACTIV Prioritization Criteria-2nd Stage Scoring Sheet-Wave 1-v2.xlsx

Dear TX-Clinical Agent Prioritization Subgroup,

I appreciate the candid and productive meeting that we had today. All your feedback is very helpful to refine our process for the next time.

For all of you working on scoring right now, please find attached a number of pieces of information that maybe helpful. Some if this some of your groups may have received before, however, I wanted to share it with the whole group for transparency and for having all of our reference data in one place. The information you will find attached is:

1. The summary spreadsheets for the agents in the host targeted category that have been added from the R&D Consortium group + 1 for [b4] as it was requested. (one note, the group shared with us [b4] is likely be tested in a few other trials, so that may need to be considered)
2. Articles on the evolving thrombosis issue that doctors are trying to deal with on the front lines. These were previously shared with the Symptomatic/Supportive therapy group.

3. An article relevant to immune modulator use in COVID-19.
4. Articles for the Antiviral group on some preclinical testing work.
5. Also for the antiviral group, the TX-Preclinical team also just sent this link with access to more screening data, which should contain all but **b4**
 - a. *“All of these compounds except **b4** are part of the ReFrame library and have been tested in a SARS-CoV-2 Vero-GFP CPE assay and posted at the ReFrame database here <https://reframedb.org/assays/A00440>. You can create an account for free and search the data.”*

Please find attached the updated spreadsheet with all the new relevant compounds added for the groups to vote on. These new compounds for your groups are highlighted in green.

Finally, please find below the captured action items and key takeaways from the meeting.

Action Items

Action Items		
	Information	POC
1	Provide Review Committee members with 5 compounds for review, along with factsheets from the R&D Consortium	Keith Gottesdiener & Elliott Levy / Stacey Adam
2	Send updated score sheets	Stacey Adam
3	Agent Prioritization Review Committee members (immunomodulators) score additional agents that have been added from the R&D Consortium list	AP Sub Group Members
4	Getting standardized, reliable data on the agents <ul style="list-style-type: none"> Trans-NIH information, intramural and extramural Mike Poole, Gates Foundation 	Stacey Adam / Ruxandra Draghia-Akli
5	Ask Preclinical Working Group (R&D members) for relevant data on agents if available	Joe Menetski
6	Get data on antivirals from NIAID and NCATS	Sarah Read/Christine Colvis

Key Takeaways

- We are re-evaluating our list for scoring and adding other agents that were inadvertently left out
- We will not go back and re-evaluate the triage list.
- Sub Group Members voicing concern on lack of confidence in agents they've had to score. More research needed on drugs to understand whether these are worth putting into clinical trials. Need for more data.
- Suggested need to understand value of the agents we are evaluating over remdesivir.

For reference tomorrow, please find attached the summary from yesterday's meeting and the agenda for tomorrow's meeting.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer
Research Partnerships

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Sent: 4/30/2020 11:09:57 PM
To: Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [b6]; Keith Gottesdiener [b6]; Elliott Levy [b6]; Wung, Peter /US [b6]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [b6]
CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: RE: Follow-up Materials to ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting #5-Including New Score Sheet (Agents Added)
Attachments: ACTIV Prioritization Criteria-2nd Stage Scoring Sheet-Wave 1-v2.xlsx; Riva2020_REFRAME drug repositioning against SARS-CoV-2.pdf; preprints202004.0149.v1.pdf; compound list caco cells.pdf; cell research 2020.pdf

Hi All,

Okay, best laid intentions. Turns out trying to get everything in one spot meant all of your networks rejected it due to the size. So this will come to you in 2-3 emails.

This will be the first. It has the score sheet and the antiviral info.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] | Mobile: [b6]

From: Adam, Stacey (FNIH) [T]

Sent: Thursday, April 30, 2020 7:05 PM

Subject: Follow-up Materials to ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting #5-Including New Score Sheet (Agents Added)

Importance: High

Dear TX-Clinical Agent Prioritization Subgroup,

I appreciate the candid and productive meeting that we had today. All your feedback is very helpful to refine our process for the next time.

For all of you working on scoring right now, please find attached a number of pieces of information that maybe helpful. Some if this some of your groups may have received before, however, I wanted to share it with the whole group for transparency and for having all of our reference data in one place. The information you will find attached is:

1. The summary spreadsheets for the agents in the host targeted category that have been added from the R&D Consortium group + 1 for Firazyr as it was requested. (one note, the group shared with us Firazyr is likely be tested in a few other trials, so that may need to be considered)
2. Articles on the evolving thrombosis issue that doctors are trying to deal with on the front lines. These were previously shared with the Symptomatic/Supportive therapy group.
3. An article relevant to immune modulator use in COVID-19.
4. Articles for the Antiviral group on some preclinical testing work.
5. Also for the antiviral group, the TX-Preclinical team also just sent this link with access to more screening data, which should contain all but EIDD-2801.
 - a. *"All of these compounds except EIDD-2801 are part of the ReFrame library and have been tested in a SARS-CoV-2 Vero-GFP CPE assay and posted at the ReFrame database here <https://reframedb.org/assays/A00440>. You can create an account for free and search the data."*

Please find attached the updated spreadsheet with all the new relevant compounds added for the groups to vote on. These new compounds for your groups are highlighted in green.

Finally, please find below the captured action items and key takeaways from the meeting.

Action Items

Action Items		
	Information	POC
1	Provide Review Committee members with 5 compounds for review, along with factsheets from the R&D Consortium	Keith Gottesdiener & Elliott Levy / Stacey Adam
2	Send updated score sheets	Stacey Adam
3	Agent Prioritization Review Committee members (immunomodulators) score additional agents that have been added from the R&D Consortium list	AP Sub Group Members
4	Getting standardized, reliable data on the agents	Stacey Adam /

- Trans-NIH information, intramural and extramural
 - Mike Poole, Gates Foundation
- Ruxandra Draghia-Akli**





5	Ask Preclinical Working Group (R&D members) for relevant data on agents if available	Joe Menetski
6	Get data on antivirals from NIAID and NCATS	Sarah Read/Christine Colvis

Key Takeaways

- We are re-evaluating our list for scoring and adding other agents that were inadvertently left out
- We will not go back and re-evaluate the triage list.
- Sub Group Members voicing concern on lack of confidence in agents they've had to score. More research needed on drugs to understand whether these are worth putting into clinical trials. Need for more data.
- Suggested need to understand value of the agents we are evaluating over remdesivir.

For reference tomorrow, please find attached the summary from yesterday's meeting and the agenda for tomorrow's meeting.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health
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fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852
   

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/30/2020 11:11:55 PM
To: Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [b6]; Keith Gottesdiener [b6]; Elliott Levy [b6]; Wung, Peter /US [b6]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [b6]
CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: RE: Follow-up Materials to ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting #5-Including New Score Sheet (Agents Added)
Attachments: lancet respiratory medicine.pdf; Amgen - Otezla (Apremilast).pdf; Takeda - Takhzyro (Lanadelumab)- summary.pdf; Takeda - Firazyr (Icatibant) -summary.pdf; Lilly-Taltz.pdf; BMS - Orencia (Apatacept).pdf; Allergan - Cenicriviroc.pdf

Hi All,

Finally, this is the third with the info sheets for the host targeted group.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Adam, Stacey (FNIH) [T]

Sent: Thursday, April 30, 2020 7:05 PM

APAR0000005557

Subject: Follow-up Materials to ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting #5-Including New Score Sheet (Agents Added)

Importance: High

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For all of you working on scoring right now, please find attached a number of pieces of information that maybe helpful. Some if this some of your groups may have received before, however, I wanted to share it with the whole group for transparency and for having all of our reference data in one place. The information you will find attached is:

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2. Articles on the evolving thrombosis issue that doctors are trying to deal with on the front lines. These were previously shared with the Symptomatic/Supportive therapy group.
3. An article relevant to immune modulator use in COVID-19.
4. Articles for the Antiviral group on some preclinical testing work.
5. Also for the antiviral group, the TX-Preclinical team also just sent this link with access to more screening data, which should contain all but [b4]
 - a. "All of these compounds except [b4] are part of the ReFrame library and have been tested in a SARS-CoV-2 Vero-GFP CPE assay and posted at the ReFrame database here <https://reframedb.org/assays/A00440>. You can create an account for free and search the data."

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2	Send updated score sheets	Stacey Adam
3	Agent Prioritization Review Committee members (immunomodulators) score additional agents that have been added from the R&D Consortium list	AP Sub Group Members
	Getting standardized, reliable data on the agents	Stacey Adam /
4	<ul style="list-style-type: none">• Trans-NIH information, intramural and extramural	Ruxandra Draghia-Akli

	<ul style="list-style-type: none"> Mike Poole, Gates Foundation 	
5	Ask Preclinical Working Group (R&D members) for relevant data on agents if available	Joe Menetski
6	Get data on antivirals from NIAID and NCATS	Sarah Read/Christine Colvis

Key Takeaways

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For reference tomorrow, please find attached the summary from yesterday's meeting and the agenda for tomorrow's meeting.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health

Direct: b6 Mobile: b6

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11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fniih.org/pandemic



From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/1/2020 2:43:13 AM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [b6]; Eisner, Mark [b6]; Gottesdiener, Keith [b6]; Hughes, Eric [b6]; Judy Carrier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [elkim@deloitte.com]; LaVange, Lisa [b6]; Levy, Elliot [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaafe06ebd70-parkeras]; Patel, Naimish [b6]; Peppercorn, Amanda [b6]; Poole, Mike [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coll]; Amanda Peppercorn [b6]; Garner, Carl [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [b6]; Jansen, Kathrin [b6]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [b6]; Biggs, Mary [b6]; Butcher, Tina [b6]; Demarcus [b6]; Macone, Erin [b6]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan [jwachtel@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Alvarez, Rosa [rosalvarez@deloitte.com];

Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [b6] Rose Li Central Account [FNIH@roseliassociates.com]; Anderson, Margaret [marganderson@deloitte.com]; Lucas Smalldon [b6]; Stratton, Benjamin [bstratton@DELOITTE.com]; [b6]; Mollica, Linda /US [b6]; Qashu, Felicia (NIH/OD) [E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]

Subject: Initial Follow-up to ACTIV Therapeutics-Clinical Working Group - Meeting #4

Attachments: ACTIV Therapeutics-Clinical WG 30Apr2020 Meeting Guide.pdf; ACTIV_Therapeutics-Clinical_Working Group Meeting 4_Key Takeaways_04302020v2.pdf

Dear TX-Clinical WG Members,

Thank you for a productive discussion today and a great cross sharing of information. Please find attached the slides from today. The initial high level summary with action items and key takeaways from the meeting. The formal summary will follow tomorrow.

In addition, please know that Tim Buchman has been kind enough to provide us the slides from the thrombosis seminar held by BARDA today. However, due to their size I have had to place them on Basecamp instead of sending directly to you. You can access our WG Basecamp site at this link:

[b5]

If you haven't already you will need to register via the link that was sent to you two weeks ago, which if you cannot find it, please let me know and I will send again.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Foundation for the National Institutes of Health

Direct: [b6] | Mobile: [b6]

fnih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/1/2020 3:19:09 AM
To: Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [b6]; Keith Gottesdiener [b6]; Elliott Levy [b6]; Wung, Peter /US [b6]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [b6]
CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bafd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: RE: Follow-up Materials to ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting #5-Including New Score Sheet (Agents Added)

Dear TX-Clinical Agent Prioritization Subgroup,

Thank you once again for a productive meeting.

I have heard from a few of you that as we discussed in the meeting you may need a little more time that until tomorrow due to the additional agents. **Therefore, we are extending the deadline for scoring until 12pm ET on Sunday, May 3.** We really cannot extend it further due to needing have a determination for an ACTIV Leadership Meeting early next week, so I would ask that everyone try to meet that deadline punctually.

I hope this will help with a little breathing room for scoring.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: b6 Mobile: b6

From: Adam, Stacey (FNIH) [T]

Sent: Thursday, April 30, 2020 7:05 PM

Subject: Follow-up Materials to ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting #5-Including New Score Sheet (Agents Added)

Importance: High

Dear TX-Clinical Agent Prioritization Subgroup,

I appreciate the candid and productive meeting that we had today. All your feedback is very helpful to refine our process for the next time.

For all of you working on scoring right now, please find attached a number of pieces of information that maybe helpful. Some if this some of your groups may have received before, however, I wanted to share it with the whole group for transparency and for having all of our reference data in one place. The information you will find attached is:

1. The summary spreadsheets for the agents in the host targeted category that have been added from the R&D Consortium group + 1 for Firazyr as it was requested. (one note, the group shared with us Firazyr is likely be tested in a few other trials, so that may need to be considered)
2. Articles on the evolving thrombosis issue that doctors are trying to deal with on the front lines. These were previously shared with the Symptomatic/Supportive therapy group.
3. An article relevant to immune modulator use in COVID-19.
4. Articles for the Antiviral group on some preclinical testing work.
5. Also for the antiviral group, the TX-Preclinical team also just sent this link with access to more screening data, which should contain all but EIDD-2801.
 - a. *"All of these compounds except EIDD-2801 are part of the ReFrame library and have been tested in a SARS-CoV-2 Vero-GFP CPE assay and posted at the ReFrame database here <https://reframedb.org/assays/A00440>. You can create an account for free and search the data."*

Please find attached the updated spreadsheet with all the new relevant compounds added for the groups to vote on. These new compounds for your groups are highlighted in green.

Finally, please find below the captured action items and key takeaways from the meeting.

Action Items

Action Items		
	Information	POC
1	Provide Review Committee members with 5 compounds for review, along with factsheets from the R&D Consortium	Keith Gottesdiener & Elliott Levy / Stacey Adam
2	Send updated score sheets Agent Prioritization Review Committee members	Stacey Adam
3	(immunomodulators) score additional agents that have been added from the R&D Consortium list	AP Sub Group Members

4	<p>Getting standardized, reliable data on the agents</p> <ul style="list-style-type: none"> • Trans-NIH information, intramural and extramural • Mike Poole, Gates Foundation 	<p>Stacey Adam /</p> <p>Ruxandra Draghia-Akli</p>
5	<p>Ask Preclinical Working Group (R&D members) for relevant data on agents if available</p>	<p>Joe Menetski</p>
6	<p>Get data on antivirals from NIAID and NCATS</p>	<p>Sarah Read/Christine Colvis</p>

Key Takeaways

- We are re-evaluating our list for scoring and adding other agents that were inadvertently left out
- We will not go back and re-evaluate the triage list.
- Sub Group Members voicing concern on lack of confidence in agents they've had to score. More research needed on drugs to understand whether these are worth putting into clinical trials. Need for more data.
- Suggested need to understand value of the agents we are evaluating over remdesivir.

For reference tomorrow, please find attached the summary from yesterday's meeting and the agenda for tomorrow's meeting.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
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11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
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CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: HOLD for ACTIV Agent Prioritization Wave 1 Final Discussion Meeting
Location: [b6]
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End: 5/3/2020 8:00:00 PM
Show Time As: Tentative

Required Attendees: Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner
Optional Attendees: Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Salathin, Carla; [b6]; Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E]; [b6]

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CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [b6]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [b6]; Ward, Jackie (NIH/NINDS) [E] [b6]
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Optional Attendees: Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Salathin, Carla; [b6] Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] [b6]

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Subject: ACTIV Agent Prioritization Wave 1 Final Discussion Meeting
Attachments: ACTIV Prioritization Criteria-2nd Stage Scoring Sheet-Wave 1-Tally.xlsx
Location: [b6]
Start: 5/3/2020 7:00:00 PM
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Optional Attendees: Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Salathin, Carla; [b6] Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] [b6]

Hi ACTIV TX-Clinical Prioritization Subgroup members,

Please find attached the final tally of scores for the agents that came through triage in Wave 1. We will use this document for our discussions today.

For those who sent me comments, I did not want to over whelm the score sheet will multiple rows of information. However, I have those and I will include them in the final record for posterity for this round. You can also feel free to bring them up during the discussion if helpful to the group.

Thanks,
Stacey

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Stratton, Benjamin [bstratton@DELOITTE.com]; Tolman, Brett [btolman@deloitte.com]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Jintanat Ananworanich [b6]

Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting
Attachments: Clinical Trial Capacity Working Group Meeting Agenda_05012020.pdf; Innovations Matrix 1May2020.xlsx
Location: [b6]
Start: 5/1/2020 1:00:00 PM
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Recurrence: Weekly
every Tuesday and Friday from 9:00 AM to 10:00 AM
Required Attendees: Srinivasan, Badhri; Vincent, Mike; Stein, Peter (FDA/CDER); Bascles, Lionel; Cohen, Myron; Corey, Larry; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshov, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; King, James; Kurilla, Mike; Nayak, Seema (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Payton, Manzone; Resnansky, Laura; Wachtel, Jonathan; Woodcock, Janet (FDA/CDER); Qashu, Felicia
Optional Attendees: Sizemore, Christine (NIH/FIC) [E]; Garner, Carlos; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Carluccio, Dana; Cheryl (FNIH) Melencio [T] [b6]; Francis Collins; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH); Tuveson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Minnich, Beth; Rebecca (NIH/NCATS) Katz [E] [b6]; Thomas, Ashley (FDA/CDER); Stratton, Benjamin; Tolman, Brett; Davey, Victoria; Jintanat Ananworanich

Attaching the most recent version of the innovations matrix. Karen

Dear Colleagues, Agenda is attached. During this call we will hear the latest from the three sub-WGs – innovations, inventory, and survey – which have been working very hard to move their activities forward quickly. Many thanks to all! We will also have a bit of a brainstorming session about creating a ‘dashboard’ to use in analyzing survey results. Best regards, Karen

ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines

Dear Clinical Trial Capacity Working Group members,

In anticipation of this working group making rapid progress on identified action items and other activities, the co-chairs have agreed that it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify areas of need, and to determine next steps. We ask that you make every effort possible to join each of these meetings, but understand that at times you may have competing priorities. To place a hold on your calendar, please accept this meeting invite with a response; later you can decline an individual meeting if you have a conflict.

An agenda and other meeting materials, as needed, will be distributed prior to each call.

With best regards,
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 5/1/2020 1:33:02 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [b6]; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Dolsten, Mikael [b6]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Hudson, Thomas [b6]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Johnson, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Kramer, Lynn [b6]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Mascola, John [b6]; Meeker, David [b6]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetski]; Pangalos, Mene [b6]; Pao, William [b6]; Paul, Steve [b6]; Perlmutter, Roger [b6]; Plump, Andy [b6]; Rasi, Guido [b6]; Reed, John [b6]; Rouse, Doris [b6]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Skovronsky, Daniel [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Stoffels, Paul [b6]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]; Tsai, John [b6]; Vessey, Rupert [b6]; Virgin, Skip [b6]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Young, John [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [b6]; Hughes, Eric [b6]; Jansen, Kathrin [b6]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa [rosalvarez@deloitte.com]; Anderson, Margaret [marganderson@deloitte.com]; Gonzalez, Nina [ningonzalez@deloitte.com]; Kim, Elizabeth [elkim@deloitte.com]; Stratton, Ben [bstratton@deloitte.com]; Tolman,

Brett [btolman@deloitte.com]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Rachel Ramoni [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d3f6cb5237a44b75887b8a1ca1f9bb91-Rachel.Ramoni]; Plenge, Robert [b6]; [b6] Cavaleri, Marco [b6]; [b6] Lee, William [b6] Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Bianchi, Diana (NIH/NICHD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e701b633c0214cb887a00d28a48e19d3-bianchidw]; Brennan, Patti (NIH/NLM) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a15fb17e820c4a418b87b86db1dfd6ff-brennanpf]; Byrnes, Noni (NIH/CSR) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c60bd8617c9f4fea9dd0d7d1e93b5223-byrnesn]; Carter, Robert (NIH/NIAMS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e9c312264ed34850bb77115bd894b5db-carterrob]; Glass, Roger (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03506bbbbb1a2472790395288d4970bc0-glassr]; Hodes, Richard (NIH/NIA) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaaf8902643342969c60fd551f81a159-hodesr]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Norris, Andrea (NIH/CIT) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1f828533385410bb4be4ea63636d1d5-norrisat]; Rodgers, Griffin (NIH/NIDDK) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33e248b6d18f42549f5af62c482de5c7-griffinrodg]; Schwetz, Tara (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b1da1e9650d44fa9a9e2d94f24b5035-schwetzta]; Sharpless, Norman (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340f3d07b6644da7aca53ab83dc066ef-sharplessne]; Tucci, Debara (NIH/NIDCD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ce882c7cb244d4e83e5ff8049a8dc65-tuccidl]; Tumminia, Santa (NIH/NEI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a748fb60f78f4712b323cac597ea06cf-tumminias]; Volkow, Nora (NIH/NIDA) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1106941d5164156bf08e25f24057a4d-nvolkow]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Lankford, David (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f29a9bef672409d967e3aa5fb36e96a-lankford]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Koob, George (NIH/NIAAA) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45a89ac3ca4e4e509cadacdf510c24ed-koobgf]; Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Valantine, Hannah (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a8b8263c5cc0442aaa0875846bd020e0-valantineh]; Gottesman, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=918c2344931542a592d00dbe83d3d5a3-gottesmm]; Woychik, Rick (NIH/NIHES) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d5f2cb03d8114450b089b7a45c81f093-woychikrp]; Cihlar, Tomas [b6]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Langevin, Helene (NIH/NCCIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbb10311b6e0462b970030434fe0e21b-langevinhm]; Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]; Gallin, John (OD) [E]

CC:

[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d4baecb56bd444b985ed10fac4e19ae8-jgallin]
Barasch, Kimberly (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Burrus-Shaw, Cyndi
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Carver, Trea (NIH) [C]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Conrad, Patricia
(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Hoffstetter, Renata
(FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e9758570bf4ca08552ea377170ec2a-hoffstetter]; Iberdemaj, Vaide
[b6]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; McManus, Ayanna
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Melencio, Cheryl (FNIH)
[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[b6]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Thomas, Ashley
(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; FNIH Central Account
[FNIH@roseliassociates.com]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Li, Rose
[b6]; Zottoli, Jessica [b6]; Lowy, Douglas (NIH/NCI) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Gladman, Jordan (NIH/OD)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=eb38a598f96f488299a655a7312138fd-gladmanjt]; Elsaid, Olivia
[oelsaid@deloitte.com]; Best, Cindy (NIH/NEI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=428b52467ed046a0b474f505750a2a80-bestc]; Bronson, Charlette (NIH/NIA)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=048d4c0b49984babaaedd3448ded4ab4-bronsonc]; Dzokoto-Pomenya,
Caroline (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=3f96013017dd4c409ccb21fe454d0f00-dzokotoc]; Hamid, Khawar (NIH/CSR)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=805b1f42695249cfb1b4243f7de59343-hamidkr]; Hardesty, Rebecca
(NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=21465ceb763947408d209aaabf10af70-hardestyrs]; Hughes, Karen (NIH/OD)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Kellton, Karen (NIH/OD)
[C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4bc40ec85bc544149c6df7b796c552dd-hamiltonkaa]; Mowery, Penny
(NIH/NIDDK) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=29d83e4b4e014dcbb9f809d52b4ee0e2-mowerypj]; New, Suzanne
(NIH/NIDCR) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=64f7f5a592b542d785d1c64d2aff6032-news1]; Ott, Sandra (NIH/NICHD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4fdd4311f07342f5af65c48cd1b53412-otts]; Salley, Jasmine (NIH/NIDDK) [C]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e4c744874a4106b835f731bd2a37e7-salleyjc]; Schulke, Hilda (NIH/NIDA)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e6e37ceffade4ea59375aab6fd35eb47-schulkeh]; Shapiro-Loser, Beth
(NIH/NIDDK) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=770c87f7a6d143c9b1f2271527db3d30-levyb]; Stover, Kathleen (NIH/FIC) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a372032e1b4999b57bc64b2e59304b-stoverka]; Togashi, Miekko (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togashim]; Wade, Portia (NIH/CIT) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=058d233dfb124f919afb5c20a0e79908-davispl2]; Barnett, Sylvia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d977e2c82aad4b6bb03079ddce7dabd4-barnettsl]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; Castillejos zenteno, Carlos [JRDUS] [b6]; Oresanya, Jejelola (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e6b58fd7ce540fba2283352ddf277e4-oresanyaj]; McBurney, Margaret (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=efd5476a884ff7bacfb38cb2805863-mmcburney]; Smith, Spencer (NIH/NIEHS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=372312fca51d410fba8895dd8b0329a9-smithdas]; Denny, Joshua (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cdb4626dabbb45aa8b8e5d21169344e6-dennyjc]; Council, Lisa (NIH/NCCIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=46e1791d0feb4292b43f48a40f4934e1-dixonlr]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Gorman, Greta (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=280703da933d491586841696e460f062-gormanmj]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]

Subject: ACTIV Response Partnership Leadership Team Meeting #3

Location: [b6]

Start: 5/6/2020 7:30:00 PM

End: 5/6/2020 9:00:00 PM

Show Time As: Busy

Dr. Burklow just forwarded the invite to Renate Myles

-----Original Appointment-----

From: Melencio, Cheryl (FNIH) [T] **On Behalf Of** Wholley, David (FNIH) [T]

Sent: Friday, April 24, 2020 11:37 AM

To: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Collins, Francis (NIH/OD) [E]; Corey, Larry; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeling, Emily (NIH/NIAID) [E]; Fauci, Anthony (NIH/NIAID) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Pangalos, Mene; Pao, William; Paul, Steve; Perlmutter, Roger; Plump, Andy; Rasi, Guido; Reed, John; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Tsai, John; Vessey, Rupert; Virgin, Skip; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Freire, Maria (FNIH) [T]; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Gonzalez, Nina; Kim, Elizabeth; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Rachel Ramoni; Plenge, Robert; Talley, Michael; Cavaleri, Marco; Lee, William; Anderson, James (NIH/OD) [E]; Bianchi, Diana (NIH/NICHD) [E]; Brennan, Patti (NIH/NLM) [E]; Byrnes, Noni (NIH/CSR) [E]; Carter, Robert (NIH/NIAMS) [E]; Glass, Roger (NIH/FIC) [E]; Hodes, Richard (NIH/NIA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Norris, Andrea (NIH/CIT) [E]; Rodgers, Griffin (NIH/NIDDK) [E]; Schwetz, Tara (NIH/OD) [E]; Sharpless, Norman (NIH/NCI) [E]; Tucci, Debara (NIH/NIDCD) [E]; Tumminia, Santa (NIH/NEI) [E]; Volkow, Nora (NIH/NIDA) [E]; Wolinetz, Carrie (NIH/OD) [E]; Lankford, David (NIH/OD)

[E]; Gibbons, Gary (NIH/NHLBI) [E]; Koob, George (NIH/NIAAA) [E]; Hallett, Adrienne (NIH/OD) [E]; Valantine, Hannah (NIH/OD) [E]; Gottesman, Michael (NIH/OD) [E]; Woychik, Rick (NIH/NIEHS) [E]; Cihlar, Tomas; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Langevin, Helene (NIH/NCCIH) [E]; Lauer, Michael (NIH/OD) [E]; Gallin, John (OD) [E]
Cc: Barasch, Kimberly (NIH/NIAID) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Conrad, Patricia (NIH/NIAID) [E]; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Lagos, Enrique (NIH/NCATS) [E]; McManus, Ayanna (NIH/OD) [E]; Melencio, Cheryl (FNIH) [T]; Protasiewicz, Ann; Simon, Dina (NIH/OD) [C]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; FNIH Central Account; Sepulveda, Dorina (FNIH) [T]; Li, Rose; Zottoli, Jessica; Lowy, Douglas (NIH/NCI) [E]; Parker, Ashley (NIH/OD) [E]; Gladman, Jordan (NIH/OD) [E]; Elsaid, Olivia; Best, Cindy (NIH/NEI) [E]; Bronson, Charlette (NIH/NIA) [E]; Dzokoto-Pomenya, Caroline (NIH/OD) [C]; Hamid, Khawar (NIH/CSR) [E]; Hardesty, Rebecca (NIH/OD) [C]; Hughes, Karen (NIH/OD) [E]; Kellton, Karen (NIH/OD) [C]; Mowery, Penny (NIH/NIDDK) [E]; New, Suzanne (NIH/NIDCR) [E]; Ott, Sandra (NIH/NICHD) [E]; Salley, Jasmine (NIH/NIDDK) [C]; Schulke, Hilda (NIH/NIDA) [E]; Shapiro-Loser, Beth (NIH/NIDDK) [E]; Stover, Kathleen (NIH/FIC) [E]; Togashi, Mieko (NIH/NCI) [E]; Wade, Portia (NIH/CIT) [E]; Barnett, Sylvia (NIH/OD) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Castillejos zenteno, Carlos [JRDUS]; Oresanya, Jejelola (NIH/OD) [C]; McBurney, Margaret (NIH/OD) [E]; Smith, Spencer (NIH/NIEHS) [E]; Denny, Joshua (NIH/OD) [E]; Council, Lisa (NIH/NCCIH) [C]; Meltzer, Abbey (FNIH) [T]; Gorman, Greta (FNIH) [T]; Myles, Renate (NIH/OD) [E]

Subject: ACTIV Response Partnership Leadership Team Meeting #3

When: Wednesday, May 6, 2020 3:30 PM-5:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: b6

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 5/1/2020 1:33:24 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd42247548e596778304f781f-austinc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [b6]; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a13b449f9f6ccb-Gary.Disbro]; Dolsten, Mikael [b6]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Hudson, Thomas [b6]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Johnson, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Kramer, Lynn [b6]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffb9ae95d631116f3-marstonhd]; Mascola, John (NIH/VRC) [E] [b6] Meeker, David [b6]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Pangalos, Mene [b6]; Pao, William [b6]; Paul, Steve [b6]; Perlmutter, Roger [b6]; Plump, Andy [b6]; Rasi, Guido [b6]; Reed, John [b6]; Rouse, Doris [b6]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Skovronsky, Daniel [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Stoffels, Paul [b6]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]; Vessey, Rupert [b6]; Virgin, Skip [b6]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Young, John [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [b6]; Hughes, Eric [b6]; Jansen, Kathrin [b6]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa [rosalvarez@deloitte.com]; Anderson, Margaret [marganderson@deloitte.com]; Gonzalez, Nina [ningonzalez@deloitte.com]; Kim, Elizabeth [elkim@deloitte.com]; Stratton, Ben [bstratton@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Rachel Ramoni [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=d3f6cb5237a44b75887b8a1ca1f9bb91-Rachel.Ramo]; Plenge, Robert
[b6]; Cavalieri, Marco
[b6] Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5];
Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Gadbois, Ellen (NIH/OD)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Tsai, John
[b6]
CC: Barasch, Kimberly (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Burrus-Shaw, Cyndi
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Carver, Trea (NIH) [C]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Conrad, Patricia
(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Hoffstetter, Renata
(FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e9758570bf4ca08552ea377170ec2a-hoffstetter]; Iberdemaj, Vaide
[b6]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; McManus, Ayanna
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Melencio, Cheryl (FNIH)
[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Protasiewicz, Ann
[b6]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Thomas, Ashley
(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Sepulveda, Dorina (FNIH) [T]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; FNIH Central Account
[FNIH@roseliassociates.com]; Li, Rose [b6]; Zottoli, Jessica [b6]
Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Gladman, Jordan (NIH/OD)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=eb38a598f96f488299a655a7312138fd-gladmanjt]; Elsaid, Olivia
[oelsaid@deloitte.com]; Castillejos zenteno, Carlos [JRDUS] [b6] Dimishkov, Roxanne (NIH/NHLBI)
[C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; Burklow, John
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Wolinetz, Carrie (NIH/OD)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Myles, Renate (NIH/OD)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Hallett, Adrienne (NIH/OD)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Chen, Helen
[qingchen@deloitte.com]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Meltzer, Abbey (FNIH) [T]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Gorman, Greta (FNIH) [T]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=280703da933d491586841696e460f062-gormanmj]; Dana Carluccio
[b6]

Subject: ACTIV Response Partnership Leadership Team Meeting #4

Attachments: Materials for June 3 ACTIV Partnership Leadership Call

Location: b6

Start: 6/3/2020 4:00:00 PM

End: 6/3/2020 5:30:00 PM

Show Time As: Busy

Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Collins, Francis (NIH/OD) [E]; Corey, Larry; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbelding, Emily (NIH/NIAID) [E]; Fauci, Anthony (NIH/NIAID) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Pangalos, Mene; Pao, William; Paul, Steve; Perlmutter, Roger; Plump, Andy; Rasi, Guido; Reed, John; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Tsai, John; Vessey, Rupert; Virgin, Skip; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Freire, Maria (FNIH) [T]; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Gonzalez, Nina; Kim, Elizabeth; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Rachel Ramoni; Plenge, Robert; Talley, Michael; b6; Cavaleri, Marco; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Gibbons, Gary (NIH/NHLBI) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]

Optional Attendees: Barasch, Kimberly (NIH/NIAID) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Conrad, Patricia (NIH/NIAID) [E]; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Lagos, Enrique (NIH/NCATS) [E]; McManus, Ayanna (NIH/OD) [E]; Melencio, Cheryl (FNIH) [T]; Protasiewicz, Ann; Simon, Dina (NIH/OD) [C]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Sepulveda, Dorina (FNIH) [T]; FNIH Central Account; Li, Rose; Zottoli, Jessica; Parker, Ashley (NIH/OD) [E]; Gladman, Jordan (NIH/OD) [E]; Elsaid, Olivia; Castillejos zenteno, Carlos [JRDUS]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Burklow, John (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Hallett, Adrienne (NIH/OD) [E]; Chen, Helen; Lowy, Douglas (NIH/NCI) [E]; Meltzer, Abbey (FNIH) [T]; Gorman, Greta (FNIH) [T]; Dana Carluccio

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/1/2020 1:36:56 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Coll]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [b6]; Keith Gottesdiener [b6]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Elliott Levy [b6]; Sandeep Menon [b6]; Amanda Peppercorn [b6]; Proschan, Michael (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [b6]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f29042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [b6]; Wung, Peter /US [b6]; Mary Biggs [b6]; Demarcus [b6]; Macone, Erin [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [b6]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Material for ACTIV TX-Clinical Master Protocol Subgroup Meeting #11
Attachments: ACTIV Therapeutics-Clinical_MP Subgroup_1May2020 Meeting Guide.pdf; ACTIV Therapeutics Clinical Master Protocol Sub-Group Meeting Agenda_05012020.pdf

Dear TX-Clinical Master Protocol Subgroup,

Please find attached the materials for today's meeting.
Please let me know if you have any questions.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer

APAR0000005548

Research Partnerships

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
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Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #11
Attachments: ACTIV Therapeutics Clinical Master Protocol Sub-Group Meeting Agenda_05012020.pdf; ACTIV Therapeutics-Clinical_MP Subgroup_1May2020 Meeting Guide.pdf
Location: [b6]
Start: 5/1/2020 3:00:00 PM
End: 5/1/2020 4:00:00 PM
Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne

(FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US
Optional Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley
Attendees: (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]

Dear TX-Clinical Master Protocol Subgroup,

Please find attached the materials for today’s meeting.
Please let me know if you have any questions.

Thanks,
Stacey

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CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: Agenda for ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #6
Attachments: ACTIV Therapeutics Clinical_Agent Prioritization Sub-Group Meeting Agenda_05012020v2.pdf

Dear TX-Clinical Agent Prioritization Subgroup,

Please find attached the agenda for today's call. We will be continuing the discussions from yesterday.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
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CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #6
Attachments: ACTIV Therapeutics Clinical_Agent Prioritization Sub-Group Meeting Agenda_05012020v2.pdf
Location: [b6]
Start: 5/1/2020 7:00:00 PM
End: 5/1/2020 8:30:00 PM
Show Time As: Tentative

Required Attendees: Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner
Optional Attendees: Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; [b6]; Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E]; [b6]

Dear TX-Clinical Agent Prioritization Subgroup,

Please find attached the agenda for today's call. We will be continuing the discussions from yesterday.

Thanks,

Stacey

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Subject: DoD invitation: note to invite Colonel Nelson Michael to the ACTIV Vaccines WG
Attachments: ACTIV Partnership Leadership Meeting QA Follow Up_20200424 final.docx

Francis

First of three for you to edit and send. Copying Ashley on all in case she wants to have a look/advise on these.

Here is note for Colonel Nelson Michael
Director, Center for Infectious Diseases Research
Walter Reed Army Institute of Research

Email: b6

Dear Colonel Michael,

I am writing to you at the suggestion of Brigadier General Michael Talley. As you know well, addressing the COVID-19 pandemic is an urgent priority for the entire biomedical research community. While the response has been broad and immediate, with many individuals and organizations already dedicated to applying their capabilities to respond, the field needs to find a way to focus and prioritize these many efforts, as there is of course a critical need for effective treatments and vaccines.

NIH has been working at the forefront of addressing the crisis, including rapidly launching its own clinical trials of therapeutics and of course working with other government agencies and individual companies on accelerated testing of vaccines and therapeutics. In order to broaden the response on April 17 we announced ACTIV, a new public-private partnership with FDA, BARDA, industry, and academic scientists to further accelerate progress against COVID and the threat of future pandemics. We have since added representatives from the Veterans Administration and, in recognition of the valuable work and capabilities of the DoD in these and other fields of medical research, approached BG Talley earlier this week to see if there would be interest in adding representatives from the Department to our partnership.

As described in the attached meeting notes (from our kick-off on April 3) we have now set up Working Groups to decide efforts in four key areas—accelerating preclinical therapeutic development, optimizing clinical therapeutic development, coordinating clinical trials capacity, and supporting effective vaccine development. At the suggestion of BG Talley, I would like to invite you to join as **a member on the Vaccines Working Group** which is being co-chaired by Doug Lowy, NCI and Kathrin Jansen, Pfizer. While this group has been meeting for several weeks, there are many decisions still be made and many areas of discussion that can benefit from your insights and expertise.

Please direct your response to this invitation to Mike Santob6 of the Foundation for the NIH, who will fill you in on the mission and progress of the Working Group and get you integrated into meeting logistics. I look forward to your contributions to this critical effort.

Best,

APAR0000006247-2444207

Sent: 5/1/2020 5:48:38 PM
To: [REDACTED] b6
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: ACTIV partnership on COVID-19
Attachments: FNIH Covid 19 meeting April 03 2020 notes.docx

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Please direct your response to this invitation to Mike Santos [REDACTED] b6 of the Foundation for the NIH, who will fill you in on the mission and progress of the Working Group and get you integrated into meeting logistics. I look forward to your contributions to this critical effort.

Best,
Francis Collins

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 5/1/2020 5:56:21 PM
To: [REDACTED] b6
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]
Subject: ACTIV partnership on COVID-19
Attachments: FNIH Covid 19 meeting April 03 2020 notes.docx

Dear Colonel Michael,

I am writing to you at the suggestion of Brigadier General Michael Talley. As you know well, addressing the COVID-19 pandemic is an urgent priority for the entire biomedical research community. While the response has been broad and immediate, with many individuals and organizations already dedicated to applying their capabilities to respond, the field needs to find a way to focus and prioritize these many efforts, as there is a critical need for effective treatments and vaccines.

NIH has been working at the forefront of addressing the crisis, including rapidly launching its own clinical trials of therapeutics and of course working with other government agencies and individual companies on accelerated testing of vaccines and therapeutics. In order to broaden the response on April 17 we announced ACTIV, a new public-private partnership with FDA, BARDA, industry, and academic scientists to further accelerate progress against COVID and the threat of future pandemics. We have since added representatives from the Veterans Administration and, in recognition of the valuable work and capabilities of the DoD in these and other fields of medical research, approached BG Talley earlier this week to see if there would be interest in adding representatives from the Department to our partnership.

As described in the attached meeting notes (from our kick-off on April 3) we have now set up Working Groups to decide efforts in four key areas—accelerating preclinical therapeutic development, optimizing clinical therapeutic development, coordinating clinical trials capacity, and supporting effective vaccine development. At the suggestion of BG Talley, I would like to invite you to join as a member on the Vaccines Working Group which is being co-chaired by Doug Lowy, NCI and Kathrin Jansen, Pfizer. While this group has been meeting for several weeks, there are many decisions still to be made and many areas of discussion that can benefit from your insights and expertise.

Please direct your response to this invitation to Mike Santos, [REDACTED] b6 of the Foundation for the NIH, who will fill you in on the mission and progress of the Working Group and get you integrated into meeting logistics. I look forward to your contributions to this critical effort.

Best,
Francis Collins

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 5/1/2020 6:13:17 PM
Subject: *ACTIV Vaccine Discussion
Location: Zoom link in the calendar entry
Start: 5/2/2020 8:00:00 PM
End: 5/2/2020 9:00:00 PM
Show Time As: Busy

Recurrence: (none)

Meeting to discuss ACTIV vaccines program

Join Zoom Meeting

b6

Meeting ID: b6

Password: b6

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US (New York)

US (Chicago)

US (San Jose)

US (Tacoma)

US (Houston)

US (San Jose)

Meeting ID: b6

Password: b6

Find your local number: b6

Hi Patty,

Thanks so much. I believe we now have agreement from everyone on 4pm tomorrow, with the completely understandable caveat about Tony's schedule. I will send an invite soon.

Thanks,
Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Conrad, Patricia (NIH/NIAID) [E] [b6]

Sent: Friday, May 1, 2020 1:31 PM

To: Santos, Michael (FNIH) [T] [b6]; Barasch, Kimberly (NIH/NIAID) [C]

[b6]

Cc: Tolman, Brett [b6]; Wood, Gretchen (NIH/OD) [E] [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Barasch, Kimberly (NIH/NIAID) [C] [b6];

Awwad, David (NIH/NIAID) [C] [b6]

Subject: RE: Call with Vaccines WG co-chairs

Hi Mike-

4 pm tomorrow should be fine. Please know that Dr. Fauci's calendar is always subject to change given he is often called to the White House. Will do our best to keep this on.

Please include both Kim and David – both cc'd here – with any calendar makers/adjustments.

Many thanks,
-patty

From: Santos, Michael (FNIH) [T] [b6]

Sent: Friday, May 1, 2020 12:35 PM

To: Conrad, Patricia (NIH/NIAID) [E] [b6]; Barasch, Kimberly (NIH/NIAID) [C]

[b6]

Cc: Tolman, Brett <btolman@deloitte.com>; Wood, Gretchen (NIH/OD) [E] [b6]; Melencio, Cheryl (FNIH) [T] [b6]

Subject: RE: Call with Vaccines WG co-chairs

Thanks, Gretchen!

Hi Patty and Kim,

Francis is trying to set up a meeting this weekend with Tony, Cliff Lane, John Mascola, Peter Marks, Kathrin Jansen, Doug Lowy, David Wholley, and me. The note below says that tomorrow is better for Tony than Sunday. Based on what I know so far, tomorrow 4pm or later seems to be the overlap in availability (pending hearing from John and Peter Marks). Would 4pm or later work for Tony?

Thanks,
Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Wood, Gretchen (NIH/OD) [E] [b6]

Sent: Friday, May 1, 2020 12:30 PM

To: Santos, Michael (FNIH) [T] [b6]

COLL0000011089-2443142

Cc: Tolman, Brett <btolman@deloitte.com>; Melencio, Cheryl (FNIH) [T] <b6>; Conrad, Patricia (NIH/NIAID) [E] <b6>; Barasch, Kimberly (NIH/NIAID) [C] <b6>

Subject: Re: Call with Vaccines WG co-chairs

Hi Mike,

Sure, I have cc'd Patty and Kim from Dr. Fauci's office. They can help.

Best wishes,

Gretchen

From: "Santos, Michael (FNIH) [T]" <b6>

Date: Friday, May 1, 2020 at 12:25 PM

To: Gretchen Wood

Cc: "Tolman, Brett" <b6> "Melencio, Cheryl (FNIH) [T]" <b6>

Subject: FW: Call with Vaccines WG co-chairs

Hi Gretchen,

It looks like we're scheduling a meeting tomorrow with Francis, Toni Fauci, Cliff Lane, John Mascola, Peter Marks, Kathrin Jansen, Doug Lowy, David Wholley, and me.

Do you have advice on how best to schedule with Toni Fauci – whom should I contact? I think I have the information to schedule with the rest of them.

Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Wholley, David (FNIH) [T] <b6>

Sent: Friday, May 1, 2020 9:22 AM

To: Santos, Michael (FNIH) [T] <b6>

Subject: FW: Call with Vaccines WG co-chairs

From: Lane, Cliff (NIH/NIAID) [E] <b6>

Sent: Friday, May 1, 2020 9:19 AM

To: Collins, Francis (NIH/OD) [E] <b6>; Wholley, David (FNIH) [T] <b6>;

Freire, Maria (FNIH) [T] <b6>; Tabak, Lawrence (NIH/OD) [E] <b6>

Parker, Ashley (NIH/OD) [E] <b6>

Cc: Wood, Gretchen (NIH/OD) [E] <b6> McManus, Ayanna (NIH/OD) [E]

<b6>

Subject: Re: Call with Vaccines WG co-chairs

2-4 is bad for me.

Cliff

From: "Collins, Francis (NIH/OD) [E]" [b6]
Date: Friday, May 1, 2020 at 9:15 AM
To: "Wholley, David (FNIH) [T]" [b6], "Freire, Maria (FNIH) [T]" [b6], Lawrence Tabak [b6], "Austin, Christopher (NIH/NCATS) [E]" [b6], "Lane, Cliff (NIH/NIAID) [E]" [b6], "Parker, Ashley (NIH/OD) [E]" [b6], "Anderson, James (NIH/OD) [E]" [b6]
Cc: "Wood, Gretchen (NIH/OD) [E]" [b6], "McManus, Ayanna (NIH/OD) [E]" [b6]
Subject: Call with Vaccines WG co-chairs

Hi David,

Tony says yes to joining. Agrees we should also have Peter Marks. Also wants John Mascola and Cliff Lane.

Saturday is better for Tony. I can make myself available anytime except 8:30 – 9:15. Can you work on that?

FC

From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
Sent: 5/1/2020 6:14:54 PM
To: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Marks, Peter (FDA/CBER) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jansen, Kathrin [b6]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Conrad, Patricia (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Barasch, Kimberly (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Awwad, David (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0a5171ce4c4d4110abfe9aebfbdafbe7-dawwad]; Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; Zottoli, Jessica [b6]; Hopps, Markay [b6]; Johnson, Maureen (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr]; Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: ACTIV vaccines discussion
Attachments: Vaccine call with NIH, NIAID, FDA, ACTIV Co-Chairs 050220.docx
Location: Zoom: [b6]
Start: 5/2/2020 8:00:00 PM
End: 5/2/2020 9:00:00 PM
Show Time As: Busy

Required Attendees: Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Fauci, Anthony (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Mascola, John (NIH/VRC) [E]; Marks, Peter (FDA/CBER); Parker, Ashley (NIH/OD) [E]; Jansen, Kathrin; Lowy, Douglas (NIH/NCI) [E]; Wholley, David (FNIH) [T]

Optional

Attendees:

Wood, Gretchen (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Conrad, Patricia (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Awwad, David (NIH/NIAID) [C]; Austin, Sarah (NIH/NIAID) [E]; Zottoli, Jessica; Hopps, Markay; Johnson, Maureen (NIH/NCI) [E]; Kozlowski, Mary (NIH/NCI) [C]; Melencio, Cheryl (FNIH) [T]

Meeting to discuss ACTIV vaccines program

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US (New York)

US (Chicago)

US (San Jose)

US (Tacoma)

US (Houston)

US (San Jose)

Meeting ID:

b6

Password:

b6

Find your local number:

b6

From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
Sent: 5/1/2020 6:14:54 PM
To: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [b6]; Fauci, Anthony (NIH/NIAID) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Mascola, John (NIH/VRC) [E] [b6]; Marks, Peter (FDA/CBER) [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Jansen, Kathrin [b6]; Lowy, Douglas (NIH/NCI) [E] [b6]; Wholley, David (FNIH) [T]
CC: Wood, Gretchen (NIH/OD) [E] [b6]; Simon, Dina (NIH/OD) [C] [b6]; Conrad, Patricia (NIH/NIAID) [E] [b6]; Barasch, Kimberly (NIH/NIAID) [C] [b6]; Awwad, David (NIH/NIAID) [C] [b6]; Austin, Sarah (NIH/NIAID) [E] [b6]; Zottoli, Jessica [b6]; Hopps, Markay [b6]; Johnson, Maureen (NIH/NCI) [E] [b6]; Kozlowski, Mary (NIH/NCI) [C] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
Subject: ACTIV vaccines discussion
Location: Zoom: [b6]
Start: 5/2/2020 8:00:00 PM
End: 5/2/2020 9:00:00 PM
Show Time As: Tentative

Required Attendees: Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Fauci, Anthony (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Mascola, John (NIH/VRC) [E]; Marks, Peter (FDA/CBER); Parker, Ashley (NIH/OD) [E]; Jansen, Kathrin; Lowy, Douglas (NIH/NCI) [E]; Wholley, David (FNIH) [T]
Optional Attendees: Wood, Gretchen (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Conrad, Patricia (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Awwad, David (NIH/NIAID) [C]; Austin, Sarah (NIH/NIAID) [E]; Zottoli, Jessica; Hopps, Markay; Johnson, Maureen (NIH/NCI) [E]; Kozlowski, Mary (NIH/NCI) [C]; Melencio, Cheryl (FNIH) [T]

Meeting to discuss ACTIV vaccines program

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Password: [b6]

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Dial by your location

[b6]

US (Germantown)
US (New York)
US (Chicago)
US (San Jose)
US (Tacoma)
US (Houston)
US (San Jose)

Meeting ID: [b6]

Password:

Find your local number:

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/1/2020 8:17:17 PM
To: Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]
Subject: RE: Meeting Forward Notification: ACTIV vaccines discussion

OK, I will let the FNIH scheduler know. Thanks

From: Simon, Dina (NIH/OD) [C] [b6]
Sent: Friday, May 1, 2020 4:12 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: Re: Meeting Forward Notification: ACTIV vaccines discussion

Yes, LAT will be attending. Thanks for checking.

D

Get Outlook for iOS

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Friday, May 1, 2020 3:47:59 PM
To: Simon, Dina (NIH/OD) [C] [b6]
Subject: RE: Meeting Forward Notification: ACTIV vaccines discussion

OK, thanks – he was not included on the invite FNIH sent but I think it may have been an oversight.

From: Simon, Dina (NIH/OD) [C] [b6]
Sent: Friday, May 1, 2020 3:46 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: Re: Meeting Forward Notification: ACTIV vaccines discussion

Hi Ashely,

Let me confirm his attendance and I will get back with you shortly.

Thanks,
Dina

Get Outlook for iOS

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Friday, May 1, 2020 3:07:21 PM
To: Simon, Dina (NIH/OD) [C] [b6]
Subject: Re: Meeting Forward Notification: ACTIV vaccines discussion

Hi Dina,

I did not see Larry included on the invite for tomorrow's vaccine meeting that FNIH sent out. Am I correct that he should be included?

I cc'd you on the invite that I forwarded for 4pm tomorrow.

Thanks,
Ashley

From: Santos, Michael (FNIH) [T] [b6]
Sent: Friday, May 1, 2020 3:00 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Meeting Forward Notification: ACTIV vaccines discussion

Hi Ashley,

My understanding of the participants (which could certainly be incomplete), in addition to you, was:

- Francis
- Tony
- Cliff
- John Mascola
- Peter Marks
- Kathrin Jansen
- Doug Lowy
- David Wholley
- Me

So that's where the invite went (plus assistants). Of course happy to have anyone else that Francis/you would like. Looking forward to the conversation.

Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Friday, May 1, 2020 2:23 PM
To: Santos, Michael (FNIH) [T] [b6]
Subject: RE: Meeting Forward Notification: ACTIV vaccines discussion

I was trying to ask but seems this went to the entire group? No apologies needed.

From: Santos, Michael (FNIH) [T] [b6]
Sent: Friday, May 1, 2020 2:22 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Meeting Forward Notification: ACTIV vaccines discussion

Hi Ashley,

Does Larry plan to join as well? Apologies that he wasn't on the initial list.

Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

-----Original Appointment-----

From: Microsoft Outlook <MicrosoftExchange329e71ec88ae4615bbc36ab6ce41109e@nih.mail.onmicrosoft.com> **On Behalf Of** Parker, Ashley (NIH/OD) [E]
Sent: Friday, May 1, 2020 2:20 PM
To: Santos, Michael (FNIH) [T]
Subject: Meeting Forward Notification: ACTIV vaccines discussion
When: Saturday, May 2, 2020 8:00 PM-9:00 PM (UTC+00:00) Monrovia, Reykjavik.
Where: Zoom: [b6]

Your meeting was forwarded

Parker, Ashley (NIH/OD) [E] has forwarded your meeting request to additional recipients.

Meeting

ACTIV vaccines discussion

Meeting Time

Saturday, May 2, 2020 4:00 PM-5:00 PM.

Recipients

Tabak, Lawrence (NIH/OD) [E]

Simon, Dina (NIH/OD) [C]

All times listed are in the following time zone: (UTC-05:00) Eastern Time (US & Canada)

Sent by Microsoft Exchange Server

From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
Sent: 5/1/2020 8:34:09 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Meeting Forward Notification: ACTIV vaccines discussion

Great, thanks. I have added him to the invite.

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Friday, May 1, 2020 4:18 PM
To: Santos, Michael (FNIH) [T] [b6]
Subject: RE: Meeting Forward Notification: ACTIV vaccines discussion

Thank you – yes, Dr. Tabak should be included.

From: Santos, Michael (FNIH) [T] [b6]
Sent: Friday, May 1, 2020 3:06 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Meeting Forward Notification: ACTIV vaccines discussion

Hi Ashley,

I do not believe anyone else (including me) can see your message. I received a notice saying that you had forwarded the invite to Dr. Tabak, but not any text along with it. The invite on my calendar doesn't contain any content other than what I sent. So I think we're all set.

Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Friday, May 1, 2020 3:03 PM
To: Santos, Michael (FNIH) [T] [b6]
Subject: RE: Meeting Forward Notification: ACTIV vaccines discussion

Hi Mike,

I will follow up with Dr. Tabak to see if needs to join and circle back with you. Can you go in the invite and remove my message – this was not intended for anyone except for you, Dr. Tabak, and his assistant.

Thank you,
Ashley

From: Santos, Michael (FNIH) [T] [b6]
Sent: Friday, May 1, 2020 3:00 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Meeting Forward Notification: ACTIV vaccines discussion

Hi Ashley,

My understanding of the participants (which could certainly be incomplete), in addition to you, was:

- Francis
- Tony
- Cliff
- John Mascola
- Peter Marks
- Kathrin Jansen
- Doug Lowy
- David Wholley
- Me

So that's where the invite went (plus assistants). Of course happy to have anyone else that Francis/you would like. Looking forward to the conversation.

Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Friday, May 1, 2020 2:23 PM
To: Santos, Michael (FNIH) [T] [b6]
Subject: RE: Meeting Forward Notification: ACTIV vaccines discussion

I was trying to ask but seems this went to the entire group? No apologies needed.

From: Santos, Michael (FNIH) [T] [b6]
Sent: Friday, May 1, 2020 2:22 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Meeting Forward Notification: ACTIV vaccines discussion

Hi Ashley,

Does Larry plan to join as well? Apologies that he wasn't on the initial list.

Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

-----Original Appointment-----

From: Microsoft Outlook <MicrosoftExchange329e71ec88ae4615bbc36ab6ce41109e@nih.mail.onmicrosoft.com> **On Behalf Of** Parker, Ashley (NIH/OD) [E]

Sent: Friday, May 1, 2020 2:20 PM

To: Santos, Michael (FNIH) [T]

Subject: Meeting Forward Notification: ACTIV vaccines discussion

When: Saturday, May 2, 2020 8:00 PM-9:00 PM (UTC+00:00) Monrovia, Reykjavik.

Where: Zoom: b6

Your meeting was forwarded

Parker, Ashley (NIH/OD) [E] has forwarded your meeting request to additional recipients.

Meeting

ACTIV vaccines discussion

Meeting Time

Saturday, May 2, 2020 4:00 PM-5:00 PM.

Recipients

Tabak, Lawrence (NIH/OD) [E]

Simon, Dina (NIH/OD) [C]

All times listed are in the following time zone: (UTC-05:00) Eastern Time (US & Canada)

Sent by Microsoft Exchange Server

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/1/2020 9:25:06 PM
To: Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [b6]; Keith Gottesdiener [b6]; Elliott Levy [b6]; Wung, Peter /US [b6]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [b6]
CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Stratton, Benjamin [bstratton@DELOITTE.com]
Subject: Follow-up from ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #6
Attachments: ACTIV Prioritization Criteria-2nd Stage Scoring Sheet-Wave 1-v3.xlsx; 2020-04-30-_TX_Clinical_WG_Agent_Prioritization_Sub-WG_Summary.pdf; ACTIV_Therapeutics-Clinical_AP Sub-Group Meeting 6_Key Takeaways_05012020v2.docx

Dear TX-Clinical Agent Prioritization Subgroup,

Thank you all for a great call! Mike, thanks especially for sharing what Gates is doing.

As discussed on the call, please find attached the new Wave 1 Score Sheet with the additional scoring category for insufficient data.

Also, please find attached the formal summary of the call yesterday and the high level notes and action items from today's call. Please let me know if you have any additions or amendments.

Happy scoring and see you all on Sunday!

Thanks,
Stacey

APAR0000005532

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

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From: Tabak, Lawrence (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02E22836B5FF4E9988E3770CFC7EE770-TABAKL]
Sent: 5/1/2020 11:33:48 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: Fwd: Update on other COVID "master protocol" efforts
Flag: Follow up

Francis Did you bring this up with Gary?
Larry

Sent from my iPhone

Begin forwarded message:

From: "Wholley, David (FNIH) [T]" [b6]
Date: May 1, 2020 at 7:12:15 PM EDT
To: "Collins, Francis (NIH/OD) [E]" [b6]
Cc: "Tabak, Lawrence (NIH/OD) [E]" [b6]
Subject: Update on other COVID "master protocol" efforts

Hi Francis,

I sat in on several of the Working Group calls today and had my daily update with my team and one with Deloitte. I learned:

- The VA is working on a master protocol for COVID; Margaret Anderson thinks Mike Milken is behind this. Karen Tountas has arranged for our VA rep on the Clinical Trial Capacity Group, Victoria Davey, to set up a call with the VA MP folks and the ACTIV MP design Sub Group Stacey Adam is leading.
- From a presentation that Mike Poole of Gates Foundation gave us, their Tx Accelerator is arranging reasonably robust testing of many of the compounds we are looking to prioritize for ACTIV, including to our surprise mAbs. We still see daylight, but differentiation will be that much more challenging.
- NHLBI is actively designing an MP in their PETAL network for anticoagulants. Thanks to Cliff Lane, we are trying to get Amy Patterson to speak to Sarah Read and Stacey so we have some chance to decently align approaches.
- NINDS is both collaborating with NHLBI and running their own protocol using their SIREN network.

We cannot control what Milken and Gates do, but it is distressing to see efforts announced within NIH that more or less completely overlap and potentially compete for the same kinds of protocols and patients that ACTIV is attempting to address. It makes the partnership overall look disorganized. In fact one of our WG co-chairs used the chat feature on Zoom to comment on the side to one of my folks during a description of one of the other side NIH institute efforts that "this is like a circus—how do these people not talk to each other?"

This is not good. While you have my commitment that we will always do what we can to make sure we communicate to others in NIH the ACTIV plans, we are going to lose control of the public narrative overall if this continues. I think there is still time to address this; I would suggest a way be found to bring these other efforts together under the ACTIV banner and brand as soon as possible.

Regards,
David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

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Sent: 5/2/2020 1:44:28 AM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [b6]; Eisner, Mark [b6]; Gottesdiener, Keith [b6]; Hughes, Erid [b6]; Judy Carrier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [elkim@deloitte.com]; LaVange, Lisa [b6]; Levy, Elliot [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [b6]; Peppercorn, Amanda [b6]; Poole, Mike [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coll]; Amanda Peppercorn [b6]; Garner, Carl [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw];
CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [b6]; Jansen, Kathrin [b6]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [b6]; Biggs, Mary [b6]; Butcher, Tina [b6]; Demarcus [b6]; Macone, Erin [b6]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan [jwachtel@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Alvarez, Rosa [rosalvarez@deloitte.com];

Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Stratton, Benjamin [bstratton@DELOITTE.com]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]

Subject: Follow-up Materials from ACTIV Therapeutics-Clinical Working Group - Meeting #4

Attachments: ACTIV Therapeutics-Clinical WG 30Apr2020 Meeting Guide.pdf; 2020-04-30_TX-Clinical_WG_Meeting_Summary-v2.pdf; ACTIV Prioritization Criteria-2nd Stage Scoring Sheet-Wave 1-v3.xlsx

Dear TX-Clinical WG Members,

I know that I say it a lot, but truly, thank you for all that you have done this week. Despite the need to improve processes and the tight timelines, you all have done so much work over the last three weeks! THANK YOU!

In follow-up to yesterday's meeting, please find attached the following materials:

1. The formal meeting summary
2. The slides that were presented (Some members wished to have them again)
3. The Agent Prioritization Scoring Sheet that has both the Triage Record and the Final Compounds that are being scored by the Agent Prioritization Committee. Please keep in mind that the ~170 agents that under went triage, we already whittled down from a list of ~400 compounds that we pulled from public data bases. We will continuously update our list from new sources and refine the information for each wave of prioritization. We will begin with the 400+ each time unless an agent is decided to be unsafe or unsuitable for COVID-19.

As always, please let me know if you have any questions or amendments to the record.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 5/2/2020 2:46:03 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
Subject: RE: Update on other COVID "master protocol" efforts

Yes: although Walter has been participating directly in some of our WG calls of late I do think a conversation with him would be important.

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Saturday, May 2, 2020 10:29 AM
To: Wholley, David (FNIH) [T] [b6]
Cc: Tabak, Lawrence (NIH/OD) [E] [b6]
Subject: RE: Update on other COVID "master protocol" efforts

This is indeed a cause for serious concern. See my note about a conversation I had with Gary Gibbons yesterday, and the need to bring NHLBI back into the tent.

Do I need to have the same conversation with Walter Koroshetz?

FC

From: Wholley, David (FNIH) [T] [b6]
Sent: Friday, May 1, 2020 7:12 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Tabak, Lawrence (NIH/OD) [E] [b6]
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Regards,
David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

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Sent: 5/2/2020 7:33:20 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Collins]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.f]; Mark Eisner [b6]; Keith Gottesdiener [b6]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Elliott Levy [b6]; Sandeep Menon [b6]; Amanda Peppercorn [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [b6]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [b6]; Wung, Peter /US [b6]; Mary Biggs [b6]; Demarcus [b6]; Macone, Erin [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [b6]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Follow-up to ACTIV TX-Clinical Master Protocol Subgroup Meeting #11
Attachments: ACTIV_Therapeutics-Clinical_MP Sub-Group Meeting 11_Key Takeaways_05012020.pdf; REMAP-COVID Simulation Document - 28 April 2020 DRAFT[1].pdf; REMAP-CAP design and rationale (in press) (1).pdf; REMAP-COVID core protocol V.2.0.pdf; ms_4-30.pdf

Dear TX-Clinical Master Protocol Subgroup,

Please find attached the follow-up materials from yesterday's meeting.

1. The summary of key takeaways and action items from the discussion. Please let us know if we have missed any thing critical.
2. The documents for REMAP-COVID for review for our conversation with that team next Friday.
 - a. REMAP-COVID core protocol
 - b. REMAP-CAP rationale
 - c. REMAP-COVID simulations

3. Meta-analysis manuscript for the combination of data from remdesivir trials that Lisa discussed from the PI at UNC. This was discussed in the context of potentially considering a partially synthetic control arm for our trial if we are having challenges with getting remdesivir for SoC.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

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Sent: 5/2/2020 7:38:15 PM
To: Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [b6]; Keith Gottesdiener [b6]; Elliott Levy [b6]; Wung, Peter /US [b6]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [b6]
CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: Follow-up to ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #6
Attachments: 2020-05-01-_TX_Clinical_WG_Agent_Prioritization_Sub-WG_Summary_RLA.pdf

Dear TX-Clinical Agent Prioritization Subgroup,

I hope you are all doing well today! I know for some of you the pull of the great weather is likely strong to go outside! I hope that you are able to do so despite our scoring task!

Just a quick reminder; please have your score sheets to me by 12pm US ET tomorrow (Sunday, May 3).

In addition, please find attached the summary of yesterday's meeting. Let me know if you have any additions or amendments that you think are critical.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health

APAR0000005523

Direct: [b6] | Mobile: [b6]

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From: Tountas, Karen (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
Sent: 5/3/2020 10:04:58 AM
To: Bascles, Lionel [b6]; Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [b6]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers, Betsy [b6]; Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshov, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshovj]; Garner, Carlos [b6]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Resnansky, Laura [b6]; Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Vincent, Mike [b6]; Wachtel, Jonathan [jwachtel@deloitte.com]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]
CC: Criffield, Robin [b6]; Hamilton, Nancy [b6]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Minnich, Beth [b6]; Mueller-Reichenstein, Petra [b6]; Quadros, Nora [b6]; Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Hill, Zoe (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [marganderson@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Carluccio, Dana [b6]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny [b6]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [b6]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveson, Nancy [b6]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [b6]; Jansen, Kathrin [b6]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group]

(FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John

b6

Subject: Summary - CT Capacity WG meeting #5

Attachments: Clinical_Trial_Capacity_Working_Group_Meeting #5_Summary_FINAL.pdf

Dear Clinical Trial Capacity Working Group Members,

Attached is the summary of meeting #5 (May 1, 2020) of the full working group. The next full working group meeting is scheduled for Tuesday, May 5 at 9 am eastern time USA.

Best regards,
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health

b6

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Sent: 5/3/2020 2:15:38 PM
To: [b6]
[b6] Baric, Ralph
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
[b6] Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
[b6] Parker, Ashley (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];
[b6] Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas /US [b6]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [b6]; Hughes, Eric [b6]; Jansen, Kathrin [b6]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Kim, Elizabeth [elkim@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Wachtel, Jonathan [jwachtel@deloitte.com]; Prabhavathi Fernandes [b6]; Diamond, Michael [b6]; Rose Li [b6]; Dana Carluccio [b6]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi

(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D
[b6]; Dave Frankowski [b4,b5]; Florence, Clint (NIH/NIAID) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Lowy, Douglas
(NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]

Subject: April 30 Preclinical meeting minutes

Attachments: Antiviral expert names MD PF.docx; 2020-04-30_Preclinical_WG_Summary d3.docx

Dear Preclinical working group participants,

Please find the minutes from the meeting on April 30th. For ease of review, I have pasted the action items below. In addition, Mike Diamond and Prabha Fernandes have collected potential members of an expert panel for preclinical asset prioritization. The bios for this group have been attached for your review.

Action Items:

- Revise the slides for presentation at the Leadership Meeting. Joe and Rosa to revise, John and Christine to review.
- Prepare slides to describe the proposed NHP strategy for discussion with the NPRC directors on Tuesday, May 5th.
- Small animal team to complete the Table of small animal models and their preferred use for prioritization and presentation to this team next week.
- Send list of Bios for the In Vitro expert panel for review to the full working group, before sending meeting requests from FNIH and Co-chairs. [document included with these minutes, thank you Michael and Prabha for putting this together].

Thank you all for a very interesting and productive meeting. Please provide any comments and suggested modifications to Joe and Rosa.

Sincerely,
Joe and Rosa

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
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To: Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [b6]; Keith Gottesdiener [b6]; Elliott Levy [b6]; Wung, Peter /US [b6]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [b6]
CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: Material for ACTIV Agent Prioritization Wave 1 Final Discussion Meeting
Attachments: [b4,b5]

Hi ACTIV TX-Clinical Prioritization Subgroup members,

Please find attached the final tally of scores for the agents that came through triage in Wave 1. We will use this document for our discussions today.

For those who sent me comments, I did not want to over whelm the score sheet will multiple rows of information. However, I have those and I will include them in the final record for posterity for this round. You can also feel free to bring them up during the discussion if helpful to the group.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

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Sent: 5/3/2020 6:30:39 PM
To: Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [b6]; Keith Gottesdiener [b6]; Elliott Levy [b6]; Wung, Peter /US [b6]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [b6]
CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: ACTIV Agent Prioritization Wave 1 Final Discussion Meeting
Attachments: ACTIV Prioritization Criteria-2nd Stage Scoring Sheet-Wave 1-Tally.xlsx
Location: [b6]
Start: 5/3/2020 7:00:00 PM
End: 5/3/2020 8:00:00 PM
Show Time As: Tentative

Required Attendees: Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner
Optional Attendees: Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Salathin, Carla; [b6] Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E]; [b6]

Hi ACTIV TX-Clinical Prioritization Subgroup members,

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Stacey

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From: Koroshetz, Walter (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E8338DD7CD432E986961F1548C5EC6-KOROSHETZW]
Sent: 5/3/2020 7:42:16 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Eric Hughes [b6] Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [b6] Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [b6] Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [b6] Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [b6] Keith Gottesdiener [b6] Elliott Levy [b6] Wung, Peter /US [b6] Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [b6]
CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Salathin, Carla [b6] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6] Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: RE: Material for ACTIV Agent Prioritization Wave 1 Final Discussion Meeting
Attachments: Cytochrome_P450_3A4_and_3A5_Known_Drug_Interaction_Chart.pdf

Fyi- drugs affected by CYP3A4
w

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Sunday, May 3, 2020 2:31 PM
To: Eric Hughes [b6] Read, Sarah (NIH/NIAID) [E] [b6] Ruxandra Draghia-Akli [b6] Mellors, John W [b6] Naimish Patel [b6] Colvis, Christine (NIH/NCATS) [E] [b6] Young, John [b6] Stein, Peter (FDA/CDER) [b6] Poole, Mike [b6] Buchman, Tim (OS/ASPR/BARDA) (CTR) [b6] Vincent, Michael [b6] Keith Gottesdiener [b6] Elliott Levy [b6] Wung, Peter /US [b6] Koroshetz, Walter (NIH/NINDS) [E] [b6] Higgs, Elizabeth (NIH/NIAID) [E] [b6] Carlos O Garner [b6]
Cc: Elizabeth Kim <elkim@deloitte.com>; Menetski, Joseph (FNIH) [T] [b6] Salathin, Carla [b6] Parker, Ashley (NIH/OD) [E] [b6] Wholley, David (FNIH) [T] [b6] Melencio, Cheryl (FNIH) [T] [b6] Lucas Smalldon [b6] Walker, Paula (NIH/NINDS) [E] [b6]

[b6]; Ward, Jackie (NIH/NINDS) [E] [b6]

Subject: Material for ACTIV Agent Prioritization Wave 1 Final Discussion Meeting

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Thanks,
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Stacey J. Adam, PhD
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From: Mellors, John W [b6]
Sent: 5/3/2020 8:04:56 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [b6]; Naimish Patel [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [b6]; Keith Gottesdiener [b6]; Elliott Levy [b6]; Wung, Peter /US [b6]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [b6]
CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Salathin, Carla [b6]; Merritt, Gabriella Marie [b6]; Romanowski, Jake [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: RE: Material for ACTIV Agent Prioritization Wave 1 Final Discussion Meeting
Attachments: EMA summary-compassionate-use-remdesivir-gilead_en.pdf

b4

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Sunday, May 3, 2020 2:31 PM
To: Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Ruxandra Draghia-Akli [b6]; Mellors, John W [b6]; Naimish Patel [b6]; Colvis, Christine (NIH/NCATS) [E] [b6]; Young, John [b6]; Stein, Peter (FDA/CDER) [b6]; Poole, Mike [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [b6]; Vincent, Michael [b6]; Keith Gottesdiener [b6]; Elliott Levy [b6]; Wung, Peter /US [b6]; Koroshetz, Walter (NIH/NINDS) [E] [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6]; Carlos O Garner [b6]
Cc: Elizabeth Kim <elkim@deloitte.com>; Menetski, Joseph (FNIH) [T] [b6]; Salathin, Carla [b6]; Merritt, Gabriella Marie [b6]; Romanowski, Jake [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [b6]; Ward, Jackie (NIH/NINDS) [E] [b6]
Subject: Material for ACTIV Agent Prioritization Wave 1 Final Discussion Meeting

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Director, Cancer
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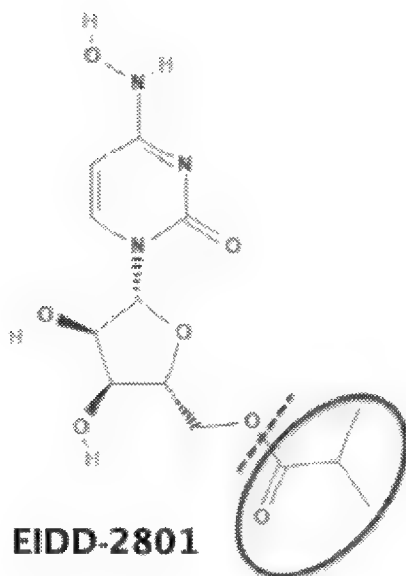
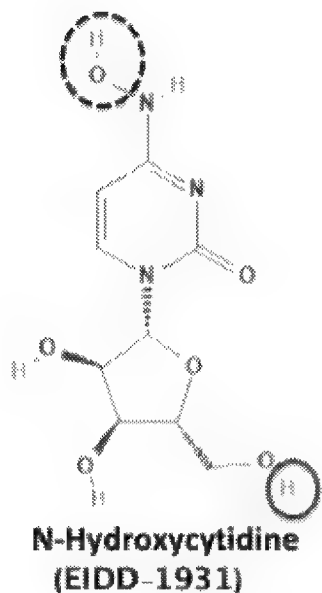
From: Buchman, Tim (OS/ASPR/BARDA) (CTR) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=00F8A853D8D740F8A8CDD55CBF8EB9DA-TIM.BUCHMAN]
Sent: 5/3/2020 8:05:36 PM
To: Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetz]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [b6]; Vincent, Michael [b6]; Keith Gottesdiener [b6]; Wung, Peter /US [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [b6]
CC: Elizabeth Kim [b6] [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: The IV form of EIDD -2801 (N4-hydroxycytidine)

Please start here:

https://news.emory.edu/stories/2020/02/coronavirus_eidd/index.htm

<https://aac.asm.org/content/62/8/e00766-18>

The underlying nucleoside is N4-hydroxycytidine ("NHC") which has active concentrations in the nanomolar to low-micromolar range and selectivity indices (SIs) (SI = CC50 [50% cytotoxic concentration]/EC50 [50% effective concentration]) of ≥ 89 against a broad panel of nasty RNA respiratory viruses.



Timothy G. Buchman, PhD, MD
 Senior Advisor
 IPA to the DRiVe (Division of Research, Innovation and Ventures)
 Biomedical Advanced Research and Development Authority (BARDA)
 Office of Assistant Secretary for Preparedness and Response (ASPR)
 U.S. Department of Health and Human Services (HHS)
 Thomas P. O'Neill, Jr. Federal Building (FOB8)
 200 C St SW
 Washington, DC 20024
 Cell: **b6**
 Email: **b6**

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From: Koroshetz, Walter (NIH/NINDS) [E] **b6**
Sent: Sunday, May 3, 2020 3:42 PM
To: Adam, Stacey (FNIH) [T] **b6**; Eric Hughes **b6**; Read, Sarah (NIH/NIAID) [E]
b6; Ruxandra Draghia-Akli **b6**; Mellors, John W **b6**; Naimish
 Patel **b6**; Colvis, Christine (NIH/NCATS) [E] **b6**; Young, John
b6; Stein, Peter (FDA/CDER) **b6**; Poole, Mike
b6; Buchman, Tim (OS/ASPR/BARDA) (CTR) **b6**; Vincent,
 Michael **b6**; Keith Gottesdiener **b6**; Elliott Levy
b6; Wung, Peter /US **b6**; Higgs, Elizabeth (NIH/NIAID) [E]
 ; Carlos O Garner **b6**
Cc: Elizabeth Kim <elkim@deloitte.com>; Menetski, Joseph (FNIH) [T] **b6**; Salathin, Carla
b6; Parker, Ashley (NIH/NCI) [F]
b6; Wholley, David (FNIH) [T] **b6**; Melencio, Cheryl (FNIH) [T]
b6; Lucas Smalldon **b6**; Walker, Paula (NIH/NINDS) [E]
b6; Ward, Jackie (NIH/NINDS) [E] **b6**
Subject: RE: Material for ACTIV Agent Prioritization Wave 1 Final Discussion Meeting

Fyi- drugs affected by CYP3A4

W

From: Adam, Stacey (FNIH) [T] [b6]

Sent: Sunday, May 3, 2020 2:31 PM

To: Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Ruxandra Draghia-Akli [b6]; Mellors, John W [b6]; Naimish Patel [b6]; Colvis, Christine (NIH/NCATS) [E] [b6]; Young, John [b6]; Stein, Peter (FDA/CDER) [b6]; Poole, Mike [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [b6]; Vincent, Michael [b6]; Keith Gottesdiener [b6]; Elliott Levy [b6]; Wung, Peter /US [b6]; Koroshetz, Walter (NIH/NINDS) [E] [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6]; Carlos O Garner [b6];
Cc: Elizabeth Kim <elkim@deloitte.com>; Menetski, Joseph (FNIH) [T] [b6]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [b6]; Ward, Jackie (NIH/NINDS) [E] [b6]

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From: Mascola, John (NIH/VRC) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F78B40A596B4CA4A2850A429D1AE3F2-JMASCOLA]
Sent: 5/4/2020 12:44:44 AM
To: Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: [EXTERNAL] RE: OK to contact Joe Menetski to discuss opportunities for alignment/ collaboration on ACTIV activities?

Agree on phase 3 timeline

That said - [b5] So not sure we can change their mind. Unlike orphan or low profit infectious diseases; [b5] much more to get there.

Regarding response – You could ask as him to stay in touch with the NIH ACTIV PPP and to stay in close touch with you and Tony of Pfizer’s progress, including which mRNA format that chose to move into advanced development – and their plans and timeline for phase 3. You will not want to be surprised by something they do.

Here is more detail:

This highlights the problem of not creating any disincentive to vaccine developers. The slowest are happy to wait for a master protocol, run by NIH and compare products – as they have nothing to lose. Pfizer, Moderna and JJ – if they are earliest to phase 3, have much less incentive.

How do we deal with this

- We need to be fast, large, adaptive – so we have a better phase 3 than anyone else.
- We let each company hold its own IND for phase 3 – which means they are in charge of their data, enabling more rapid BLA filing, or EUA by FDA. The data can still be in central database shared with NIH for sure.
- We are flexible on placebo groups and how we share placebo group. One possibility is independent but harmonized phase 3 studies, with shared rolling placebo group. So each company is assured it has a phase 3 study that enables them to get to BLA, and NIH still gets to compare multiple vaccines

Regarding several vaccine formats: he means that BioNTech – the mRNA company that makes the vaccine and has partnered with Pfizer – is testing several mRNA formats, including nucleoside silencing of mRNA (like Moderna) and self-replicating mRNA – using alphavirus replication mechanism to “replicate” many + strand mRNA molecules – allowing more protein to be produced. VRC has tested both formats in NHP, and both work well. So Pfizer will do several phase 1 studies and pick the best one. Moderna has > 10 phase 1 studies – all robustly immunogenic – so we know their format work. BioNTech is a very good mRNA company – so I would be surprised if one of their formats does not work well – but likely, Pfizer will not share the phase 1 until they are ready.

Apologies for long email – may be useful to loop Peter Marks into some of these issues – I think we CAN tackle them as we go – but we absolute need to get initial phase 3 started in July.

John

From: Lane, Cliff (NIH/NIAID) [E] [b6]
Sent: Sunday, May 3, 2020 8:36 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Mascola, John (NIH/VRC) [E] [b6]; Fauci, Anthony (NIH/NIAID) [E] [b6]
Tabak, Lawrence (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: Re: [EXTERNAL] RE: OK to contact Joe Menetski to discuss opportunities for alignment/ collaboration on ACTIV activities?

I think we could work with everyone to get a protocol written and ready to implement by the end of June with the right focus.

Cliff

On May 3, 2020, at 8:03 PM, Collins, Francis (NIH/OD) [E] [b6] wrote:

Hi John, Cliff, and Tony,

See note below, where Mikael Dolsten indicates Pfizer is planning to initiate Phase II/III of their vaccine before July. He intends to discuss our master protocol possibility with Kathrin Jensen. I am not quite sure what he means by "several vaccine formats".

Does this timetable sound realistic?

Any suggestion about a response?

Francis

From: Dolsten, Mikael [b6]
Sent: Sunday, May 3, 2020 6:26 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: Re: [EXTERNAL] RE: OK to contact Joe Menetski to discuss opportunities for alignment/ collaboration on ACTIV activities?

Hi Francis

We certainly enjoy taking part in ACTIV

I will check if we did get our drugs on the lists below

Concerning the Vaccines master protocol, by July we will hopefully be far into a potential pivotal phase 2/3 study w our vaccine platform and its most advanced candidates.

We dont want to slow down to wait for a basket trial. I think we have a possible chance to be crossing the finish line way before the time lines shared by JnJ and Sanofi and provide data on a potential safe and effective vaccine in Q3 for Potential use at large scale. I assume the urgency to have an emergency use or accelerated approval vaccine in USA is priority 1, of its safe and projected effective.

I will discuss w Kathrin Jansen if we may have an option to add one of our several vaccine formats that is less advanced or a refined format of our most advanced in the master protocol etc

b4

Happy to discuss w you and welcome your advice
Mikael

Mikael Dolsten, M.D., Ph.D.
Chief Scientific Officer and President,
Worldwide Research, Development and Medical
Pfizer Inc.
235 East 42nd Street
New York, NY 10017

On May 3, 2020, at 5:16 PM, Collins, Francis (NIH/OD) [E] **b6** wrote:
Mats

Hi Mikael,

Thanks for your note and this update on exciting progress on several fronts. ACTIV is moving forward with gratifying speed and commitment. With regard to vaccines, tomorrow the ACTIV vaccines WG will be discussing a master protocol for a phase II/III trial with adaptive design, multiple arms, and a shared placebo arm, aiming to launch on or about July 1. FDA is strongly supportive. The Moderna, Sanofi, and JnJ vaccines are likely to be included – might Pfizer also join?

The protease inhibitor sounds really exciting – I trust that compound is on the list of therapeutic candidates that the Clinical Therapeutics WG of ACTIV is reviewing? They are supposed to put forward a tentative list for the Wednesday Leadership Group meeting. Ditto with the **b4** option!

Looking forward to catching up soon!

Best, Francis

From: Dolsten, Mikael **b6**
Sent: Sunday, May 3, 2020 12:06 PM
To: Collins, Francis (NIH/OD) [E] **b6**
Subject: Re: [EXTERNAL] RE: OK to contact Joe Menetski to discuss opportunities for alignment/ collaboration on ACTIV activities?

Hi Francis

I trust you are well but likely working too many hours as we all experience in the difficult Covid times.

In the vaccine space we have progressed rapidly and are already in phase 1/2 studies dose escalation phase testing multiple format of mRNA vaccine [b4]

[b4]

In the anti-viral areas we are heading towards IND filing w a first in class potent protease inhibitor broadly inhibiting Coronavirus and very potent on SARSCov2.

We also want to start P2 studies w an [b4]
[b4]

[b4] I would be keen to know if there are suitable NIH studies for our [b4] to tap into , very unique mechanism and we have experience of good safety from phase 2 in RA.

We will soon start a US study at Yale but would be good to tap into additional options , particularly after the failed IL6 mAb, it is suggested that broader or different mechanisms are required for profound clinical effects during advanced Covid at or prior to SARDS stage .

How are things going w ACTIV.
Any issues to discuss ?

I hope our PFE representatives in ACTIV are helping out well

Pls let me know if there is anything particular to discuss or I can help you with

Best personal regards
Mikael

Sent from my iPhone

On May 3, 2020, at 10:49, Collins, Francis (NIH/OD) [E]
[b6] wrote:

Hi Morten,

Thanks for your note. It would be great to have this connection – but let me suggest that you start with David Wholley (cc'd here), as he oversees all four of the ACTIV working groups. Joe is the program lead for the group on preclinical therapeutics/repurposing.

Best, Francis

From: Sogaard, Morten [b6]
Sent: Sunday, May 3, 2020 10:46 AM
To: Collins, Francis (NIH/OD) [E] [b6]

Cc: Dolsten, Mikael [b6]; Prof Trevor M Jones
CBE FMedSci [b6] Sogaard, Morten
[b6]

Subject: OK to contact Joe Menetski to discuss opportunities for alignment/ collaboration on ACTIV activities?

Francis,

I hope you are having a good weekend.

Quick question: Would you be OK if I/we reached out to Joe Menetski, who I understand leads many of the ACTIV efforts. We have come to know Joe very well as a great collaborator on the AMP gene therapy initiative and It would be very easy I think working informally with Joe to look a bit more under the hood and identify/ map opportunities for alignment with the other initiatives.

All the Best,
Morten

From: Koroshetz, Walter (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E8338DD7CDCD432E986961F1548C5EC6-KOROSHETZW]
Sent: 5/4/2020 1:21:51 AM
To: Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [b6]; Naimish Patel [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [b6]; Keith Gottesdiener [b6]; Elliott Levy [b6]; Wung, Peter /US [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [b6]
CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Salathin, Carla [b6]; Merritt, Gabriella Marie [GMM76@pitt.edu]; Romanowski, Jake [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: RE: Material for ACTIV Agent Prioritization Wave 1 Final Discussion Meeting

Thanks very much John. Had a stupid question.

The drug was obviously built for HIV which requires activity throughout the body. Has anyone considered whether for COVID-19 a nebulized administration down the trachea into the lung would enable more potent effects given that is the site of first viral entry? Maybe enable higher doses without untoward effects.

Reason to consider checking this for other anti-virals given in early stages of the illness?

Walter

From: Mellors, John W [b6]
Sent: Sunday, May 3, 2020 4:05 PM
To: Adam, Stacey (FNIH) [T] [b6]; Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Ruxandra Draghia-Akli [b6]; Naimish Patel [b6]; Colvis, Christine (NIH/NCATS) [E] [b6]; Young, John [b6]; Stein, Peter (FDA/CDER) [b6]; Poole, Mike [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [b6]; Vincent, Michael [b6]; Keith Gottesdiener [b6]; Elliott Levy [b6]; Wung, Peter /US [b6]; Koroshetz, Walter (NIH/NINDS) [E] [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6]; Carlos O Garner [b6]

Cc: Elizabeth Kim [b6]; Menetski, Joseph (FNIH) [T] [b6]; Salathin, Carla [b6]; Merritt, Gabriella Marie [b6]; Romanowski, Jake [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [b6]; Ward, Jackie (NIH/NINDS) [E] [b6]
Subject: RE: Material for ACTIV Agent Prioritization Wave 1 Final Discussion Meeting

b4

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Sunday, May 3, 2020 2:31 PM
To: Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Ruxandra Draghia-Akli [b6]; Mellors, John W [b6]; Naimish Patel [b6]; Colvis, Christine (NIH/NCATS) [E] [b6]; Young, John [b6]; Stein, Peter (FDA/CDER) [b6]; Poole, Mike [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [b6]; Vincent, Michael [b6]; Keith Gottesdiener [b6]; Elliott Levy [b6]; Wung, Peter /US [b6]; Koroshetz, Walter (NIH/NINDS) [E] [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6]; Carlos O Garner [b6]
Cc: Elizabeth Kim <elkim@deloitte.com>; Menetski, Joseph (FNIH) [T] [b6]; Salathin, Carla [b6]; Merritt, Gabriella Marie [b6]; Romanowski, Jake [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [b6]; Ward, Jackie (NIH/NINDS) [E] [b6]
Subject: Material for ACTIV Agent Prioritization Wave 1 Final Discussion Meeting

Hi ACTIV TX-Clinical Prioritization Subgroup members,

Please find attached the final tally of scores for the agents that came through triage in Wave 1. We will use this document for our discussions today.

For those who sent me comments, I did not want to over whelm the score sheet will multiple rows of information. However, I have those and I will include them in the final record for posterity for this round. You can also feel free to bring them up during the discussion if helpful to the group.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

Join Zoom Meeting

b6

Meeting ID: [b6]

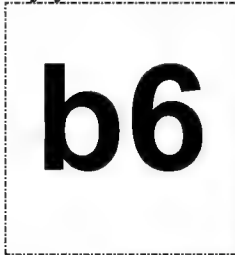
Password: [b6]

One tap mobile

b6

US (Chicago)
US (New York)

Dial by your location



- US (Chicago)
- US (New York)
- US (Germantown)
- US (Houston)
- US (San Jose)
- US (San Jose)
- US (Tacoma)

Meeting ID: **b6**

Password: **b6**

Find your local number: **b6**

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 5/4/2020 12:23:24 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: FW: [EXTERNAL] RE: OK to contact Joe Menetski to discuss opportunities for alignment/ collaboration on ACTIV activities?

Interesting response from Dolsten....

From: Dolsten, Mikael [b6]
Sent: Monday, May 4, 2020 8:15 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Fauci, Anthony (NIH/NIAID) [E] [b6]; Mascola, John (NIH/VR) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Lowy, Douglas (NIH/NCI) [E] [b6]; Jansen, Kathrin [b6]
Subject: Re: [EXTERNAL] RE: OK to contact Joe Menetski to discuss opportunities for alignment/ collaboration on ACTIV activities?

Francis
Thanks for the response

We appreciate the federal initiative and opportunity to influence it's design . I know Kathrin Jansen (ccd here) from PFE is working w the team on this.

We aim to participate in the master protocol in addition to our ongoing trial and will select the most timely vaccine format . It's great to be collaborating w NIH-FDA for the best of our nation and global health .

In the master protocol , I hope the working committee is discussing both endpoints, inclusion criteria and prime /booster for sustainability etc . mRNA and protein based vaccines have the opportunity [b4]

b4

b4

These are just two examples we can discuss on Wednesday in the leadership meeting of times permits .

In the therapeutic section , it may be worthwhile to consider what grid for selecting the compounds was used and how did the targets/drugs score . There are a number of scientific and drug development dimensions that seem to predict the probability for a drug to be active . In addition to the strength of the scientific rational , preclinical -clinical/genetic evidence we have seen that outcome of prior clinical trial predicts probability of the next eg is the biology targeted active in human disease and did the specific drug deliver a robust signal . Unfortunately drugs that fail one or two indications have low probability to be successful . There are of course always an exception to any rule :-). I am sure the sub-teams have had rich such dialogues and the leadership meeting can learn or probe in this matter as part of quality review

I look forward to the meeting

Best
Mikael
Sent from my iPhone

On May 4, 2020, at 04:26, Collins, Francis (NIH/OD) [E] [b6] wrote:

Hi Mikael,

Wow, sounds like you are making fantastic progress with the vaccine program, and we would certainly not want to do anything to slow you down! I understand that you are evaluating several mRNA formats with BioNTech. If one of those turned out to be ready for phase II/III in late June, we would be most interested in the possibility of including that in the master protocol. Please keep Tony and me in touch with Pfizer's progress, including which mRNA format you choose to move into advanced development.

Hope to hear your voice at the ACTIV Leadership Group meeting on Wednesday. There will be a lot to talk about!

Best, Francis

From: Dolsten, Mikael [b6]
Sent: Sunday, May 3, 2020 6:26 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: Re: [EXTERNAL] RE: OK to contact Joe Menetski to discuss opportunities for alignment/ collaboration on ACTIV activities?

Hi Francis

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I will check if we did get our drugs on the lists below

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We dont want to slow down to wait for a basket trial. I think we have a possible chance to be crossing the finish line way before the time lines shared by JnJ and Sanofi and provide data on a potential safe and effective vaccine in Q3 for Potential use at large scale. I assume the urgency to have an emergency use or accelerated approval vaccine in USA is priority 1, of its safe and projected effective.

I will discuss w Kathrin Jansen if we may have an option to add one of our several vaccine formats that is less advanced or a refined format of our most advanced in the master protocol etc

If we can agree about shared key endpoints , we can include that cross all studies Whether master protocol or more advanced sponsor trials which helps comparison

Happy to discuss w you and welcome your advice
Mikael

Mikael Dolsten, M.D., Ph.D.
Chief Scientific Officer and President,
Worldwide Research, Development and Medical
Pfizer Inc.
235 East 42nd Street
New York, NY 10017

On May 3, 2020, at 5:16 PM, Collins, Francis (NIH/OD) [E] b6 wrote:
Mats

Hi Mikael,

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The protease inhibitor sounds really exciting – I trust that compound is on the list of therapeutic candidates that the Clinical Therapeutics WG of ACTIV is reviewing? They are supposed to put forward a tentative list for the Wednesday Leadership Group meeting. Ditto with the b5 option!

Looking forward to catching up soon!

Best, Francis

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Subject: Re: [EXTERNAL] RE: OK to contact Joe Menetski to discuss opportunities for alignment/ collaboration on ACTIV activities?

Hi Francis

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[REDACTED] b5

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We also want to start P2 studies w an [REDACTED] b5

[REDACTED] b5

I would be keen to know if there are suitable NIH studies for our [REDACTED] b5 to tap into , very unique mechanism and we have experience of good safety from phase 2 in RA.

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How are things going w ACTIV.
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Sent from my iPhone

On May 3, 2020, at 10:49, Collins, Francis (NIH/OD) [E]

[REDACTED] b6 wrote:

Hi Morten,

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Best, Francis

From: Sogaard, Morten <[REDACTED] b6 >

Sent: Sunday, May 3, 2020 10:46 AM

To: Collins, Francis (NIH/OD) [E] [REDACTED] b6

Cc: Dolsten, Mikael [b6] Prof Trevor M Jones
CBE FMedSci [b6] Sogaard, Morten
[b6]

Subject: OK to contact Joe Menetski to discuss opportunities for alignment/ collaboration on ACTIV activities?

Francis,

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Quick question: Would you be OK if I/we reached out to Joe Menetski, who I understand leads many of the ACTIV efforts. We have come to know Joe very well as a great collaborator on the AMP gene therapy initiative and It would be very easy I think working informally with Joe to look a bit more under the hood and identify/ map opportunities for alignment with the other initiatives.

All the Best,
Morten

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/4/2020 1:35:57 PM
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CC: Mary Biggs [b6]; Demarcus [b6] Macone, Erin [b6] Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [b6] Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Materials for ACTIV TX-Clinical Master Protocol Subgroup Meeting #12
Attachments: ACTIV Therapeutics-Clinical_MP Subgroup_4May2020 Meeting Guide.pdf; ACTIV Therapeutics Clinical Master Protocol Sub-Group Meeting 4May2020 Agenda.pdf

Dear TX-Clinical Master Protocol Subgroup,

Please find attach the materials for today's meeting.

1. Agenda
2. Slides

Thanks,

APAR0000005508

Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

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CC: Mary Biggs [b6]; Demarcus [b6]; Macone, Erin [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [b6]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #12
Attachments: ACTIV Therapeutics-Clinical_MP Subgroup_4May2020 Meeting Guide.pdf; ACTIV Therapeutics Clinical Master Protocol Sub-Group Meeting 4May2020 Agenda.pdf
Location: [b6]
Start: 5/4/2020 5:00:00 PM
End: 5/4/2020 6:00:00 PM
Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butters; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Koroshetz, Walter (NIH/NINDS) [E]

Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]

Dear TX-Clinical Master Protocol Subgroup,

Please find attach the materials for today's meeting.

1. Agenda
2. Slides

Thanks,
Stacey

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CC: Mary Biggs [b6]; Demarcus [b6]; Macone, Erin [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [b6]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

Subject: ACTIV TX-Clinical Master Protocol Ad Hoc Meeting

Location: [b6]

Start: 5/5/2020 6:00:00 PM

End: 5/5/2020 7:00:00 PM

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Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne

(FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Koroshetz, Walter (NIH/NINDS) [E]

Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
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CC: Mary Biggs [b6]; Demarcus [b6]; Macone, Erin [b6]; Tountas, Karen (FNIH) [T]; [b6]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina [b6]; Wholley, David (FNIH) [T]; [b6]; Melencio, Cheryl (FNIH) [T]; [b6]; Hoots, W. Keith (NIH/NHLBI) [E]; [b6]
Subject: ACTIV TX-Clinical Master Protocol Ad Hoc Meeting
Location: [b6]
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End: 5/5/2020 7:00:00 PM
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Required Attendees: Adam, Stacey (FNIH) [T]; Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Koroshetz, Walter (NIH/NINDS) [E]; Patterson, Amy (NIH/NHLBI) [E]
Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Hoots, W. Keith (NIH/NHLBI) [E]

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To: Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [b6]; Keith Gottesdiener [b6]; Elliott Levy [b6]; Wung, Peter /US [b6]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [b6]
CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: Follow-up from ACTIV Agent Prioritization Wave 1 Final Discussion Meeting
Attachments: 2020-05-03_TX-Clinical_WG_Agent_Prioritization_Subgroup_Summary.pdf

Hi ACTIV TX-Clinical Prioritization Subgroup members,

Thank you all once again for a very productive meeting yesterday, and especially thank for the extra hour and a half that you gave to the discussion. I appreciate that you helped us get to a good set of selections for our first round and that you helped us learn a lot about how to refine the process.

Please find attached the official summary of yesterday's call. Please let me know if you feel and additions or amendments are needed to accurately reflect the record of our discussions. Please keep in mind that this will be the official record of our first meeting, so review with that eye for any necessary details.

We will send the materials out for tomorrow's call tomorrow AM, but the main focus of our call will be to debrief on our final review meeting and suggestions for improving the next round.

Thanks,
Stacey

Stacey J. Adam, PhD

APAR0000005506

Director, Cancer
Research Partnerships

Direct:

b6

Mobile:

b6

From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Stratton, Benjamin [bstratton@DELOITTE.com]; Tolman, Brett [btolman@deloitte.com]; Garner, Carlos [b6]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Jintanat Ananworanich [b6]

Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting
Attachments: Clinical Trial Capacity Working Group Meeting Agenda_05052020.pdf; Network survey responses 04 May 2020.pdf; Site survey responses 04May2020.pdf; DRAFT CRO survey.docx
Location: [b6]
Start: 5/5/2020 1:00:00 PM
End: 5/5/2020 2:00:00 PM
Show Time As: Tentative

Recurrence: Weekly
every Tuesday and Friday from 9:00 AM to 10:00 AM
Required Attendees: Stein, Peter (FDA/CDER); Vincent, Mike; Woodcock, Janet (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Bascles, Lionel; Cohen, Myron; Corey, Larry; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshov, James (NIH/NCI) [E]; King, James; Kurilla, Mike; Nayak, Seema (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Payton, Manzone; Resnansky, Laura; Srinivasan, Badhri; Wachtel, Jonathan; Qashu, Felicia
Optional Attendees: Sizemore, Christine (NIH/FIC) [E]; Kenny, Dermot; Anderson, Margaret; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Carluccio, Dana; Cheryl (FNIH) Melencio [T] [b6]; Francis Collins; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH); Tuveson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Minnich, Beth; Rebecca (NIH/NCATS) Katz [E] [b6]; Thomas, Ashley (FDA/CDER); Stratton, Benjamin; Tolman, Brett; Garner, Carlos; Davey, Victoria; Jintanat Ananworanich

Dear Colleagues,

Attached is the meeting agenda along with current survey results [b5]. In addition, attached are draft questions to consider for the CRO survey that will be discussed, but please note that some questions are carried over from the network survey for consideration (editing or deleting). Best regards, Karen

ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines

Dear Clinical Trial Capacity Working Group members,

In anticipation of this working group making rapid progress on identified action items and other activities, the co-chairs have agreed that it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify areas of need, and to determine next steps. We ask that you make every effort possible to join each of these meetings, but understand that at times you may have competing priorities. To place a hold on your calendar, please accept this meeting invite with a response; later you can decline an individual meeting if you have a conflict.

An agenda and other meeting materials, as needed, will be distributed prior to each call.

With best regards,
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
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CC: Mary Biggs [b6]; Demarcus [b6]; Macone, Erin [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [b6]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Chertow, Jessica (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=742e0637f5da45aa9bde0d9de07a80d8-chertowjh]; Paltoo, Dina (NIH/NLM) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afbb60a3cbcd495aa92790a75dc3ffd6-paltoo]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]
Subject: Follow-up to ACTIV TX-Clinical Master Protocol Subgroup Meeting #12

Dear TX-Clinical Master Protocol Subgroup and Invited Guests,

Thank you all for a very productive meeting today! We want to especially thank our NHLBI/NINDS colleagues that came into speak with us about their master protocol that they have been working to launch the last few weeks. The information was most helpful for our discussions. We appreciate you taking the time.

As usual, please find the high level quick summary and action items from our meeting today. For the benefit of our guests, we take just a quick high level running summary versus a formal meeting write-up for these meetings, since try to turn it around the same day.

Please let me know any amendments or additions you may wish to note for us to make.

Again, thank you all for joining us. We look forward to close collaboration between our two groups.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
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Subject: RE: ACTIV TX-Clinical Master Protocol Ad Hoc Meeting
Attachments: recovery-protocol-v3-0-2020-04-07.pdf; ACTT2 - IND 147771 SN00eb 5.3.5.1 Protocol No. 20-0006 - v4.0, 19Apr2020.eCTD.pdf; ACTIV Therapeutics-Clinical_MP Subgroup_4May2020 Meeting Guide.pdf

Dear TX-Clinical Master Protocol Subgroup members,

For the meeting that we have set tomorrow, we will be using the same slides from today since we did not get a chance to full finish our discussion. (Attached again here for you reference. The agenda slide will be updated for tomorrow.)

Tomorrow will be a pretty heavy stats and protocol design discussion so please come prepared to think through our options.

As food for thought if we do decide to move in the direction of a factorial design, I am attaching here the RECOVERY protocol from the UK, which uses a complex design such as this and is a large confirmatory style trial such as that we are considering. This may not be exactly what we need, but it could be a counterpoint to the ACTT-2 protocol that we have been evaluating and which I attach again here for ease of reference. Keep in mind that either option we choose will require modification for our purposes. We have already begun this for the ACTT protocol, but we may be able to incorporate additional design ideas from others.

I look forward to a very productive discussion tomorrow. Thank you for being willing to meet between our normally scheduled meetings.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

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CC: Tolman, Brett [btolman@deloitte.com]; Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; [b6] Johnson, Maureen (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr]; Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; [b6] Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Douoguih, Macaya [JRDUS]; [b6] Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Gilbert PhD, Peter B [b6] Paul Gillard [b6]; Gruber, Marion (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ebf7a8eb8dd541b2883a966ea5afd809-GRUBER.fda]; Gurunathan, Sanjay /US [b6] Hamilton, Holli (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a28fc2f8eb134b00b5aaa4222d0576cc-Holli.Hamil]; [b6] Ledgerwood, Julie (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5dc9f31ded594eff8ac506d2c4103c15-ledgerwood]; Leyssen, Maarten [JRDNL]; [b6] Marovich, Mary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bfd0192d165d4643accf6347728dbaeb-marovichma]; Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33958e1252cf4266bffc8d94988f5715-kneuzil.com]; Robb, Merlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17bbdb1e858542e7b5959ec7aeb7679a-mrobb.hivre]; [b6] Michael Watson (x); [b6] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; [b6] Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; john.young.jy3@roche.com; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Kim, Elizabeth [elkim@deloitte.com]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@DELOITTE.com]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Stratton, Benjamin [bstratton@DELOITTE.com]

Subject: Agenda and Materials for ACTIV Vaccines Working Group meeting: Today, 5 May

Attachments: 2020-05-05 Vaccines Working Group Visuals.pptx; ACTIV Vaccines Clinical Trials Sub-Group roster - 4 May 2020.docx; 2020-05-04 Vaccines Clinical Trials Sub-Group meeting Notes.docx

Dear Vaccines Working Group,

We are looking forward to our next Vaccines Working Group meeting with you, today (Tuesday) at 12pm ET (9am PT / 6pm CEST). The key agenda items for our meeting are:

- Review new mandates for the Working Group
- Discuss pathways to approval/authorization using correlates and other evidence
- Share ACTIV external communications approach

The slides that we will use during the meeting are attached, with some additional slides drawn from the presentation Marion Gruber shared (attached in full in Friday's notes) in an appendix for reference.

We also want to share an update related to the first agenda item. The Vaccines Clinical Trials Sub-Group met for the first time yesterday (Monday). Much as we anticipate the master protocol trial doing, we rapidly enrolled participants (though perhaps with limited informed consent) in this Sub-Group; the roster as of today is attached, with some additional invitations pending. We have also attached the notes from that meeting.

As always, please do not hesitate to reach out with any input or questions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]

Sent: Sunday, May 3, 2020 5:45 PM

Subject: Vaccines Working Group important update: Clinical Trial plans

Dear Vaccines Working Group,

Yesterday evening there was an exciting expansion of the opportunity for the Vaccines Working Group to contribute to accelerating vaccine development. We learned that there will be US government funding for a master protocol phase 2/3 adaptive vaccine efficacy trial, with provisions to add and drop vaccine candidate arms over time.

The Clinical Trial Sub-Group (slight name change) will be tasked with supporting this master protocol trial, including the protocol and the networks/sites implementation. The goal is to have this trial ready to start by July 1, though there may be an opportunity to start in June if the work can be completed by then.

This is a significant expansion of scope for the Sub-Group. Given the magnitude of this responsibility, we will be asking for additional representation on the Sub-Group and pulling in expertise, including some of the master protocols experts that have been writing the ACTIV therapeutics protocols. The first meeting of the Sub-Group is tomorrow at 10am ET (7am PT / 4pm CEST).

We will also discuss this at the Vaccines Working Group meeting on Tuesday at 12pm ET (9am PT / 6pm CEST). Please don't hesitate to reach out with any questions.

Best regards,
Mike, for the Vaccines Working Group

Michael Santos, PhD
Associate Vice President, Science
Foundation for the National Institutes of Health
b6 fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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Subject: Canceled: ACTIV Preclinical working group (Tuesday meeting)

Location: [b6]

Start: 5/5/2020 6:00:00 PM

End: 5/5/2020 7:00:00 PM

Show Time As: Free

Recurrence: Weekly
every Tuesday from 2:00 PM to 3:00 PM

Required Attendees: [b6]

[b6]

Parker,

Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas

Optional Attendees: Florence, Clint (NIH/NIAID) [E]; Diamond, Michael; Gonzalez, Nina; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]

Cancelling due to the NPRC director's meeting.

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: Materials for ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #7
Attachments: ACTIV Therapeutics Clinical_Agent Prioritization Sub-Group Meeting 05May2020 Agenda.pdf; ACTIV Therapeutics-Clinical_AP Subgroup_4May2020 Meeting Guide.pdf

Dear TX-Clinical Agent Prioritization Subgroup,

Please find attached the materials for today's meeting. My apologies for the late distribution.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
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CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bafd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #7
Attachments: ACTIV Therapeutics-Clinical_AP Subgroup_4May2020 Meeting Guide.pdf; ACTIV Therapeutics Clinical_Agent Prioritization Sub-Group Meeting 05May2020 Agenda.pdf
Location: [b6]
Start: 5/5/2020 5:00:00 PM
End: 5/5/2020 6:00:00 PM
Show Time As: Tentative

Required Attendees: Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E]
Optional Attendees: Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] [b6]

Dear TX-Clinical Agent Prioritization Subgroup,

Please find attached the materials for today's meeting. My apologies for the late distribution.

Thanks,
Stacey

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From: Wung, Peter /US [b6]
Sent: 5/5/2020 5:50:49 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Patel, Naimish /US [b6] Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [b6]; Keith Gottesdiener [keith.gottesdiener@gmail.com]; Elliott Levy [b6]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [b6]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla [carla.salathin@novartis.com]; GMM76@pitt.edu; JKR31@pitt.edu; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bafd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: RE: ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #7
Attachments: Coagulopathy COVID Blood Apr 2020.pdf

Dear All:

This is really excellent review article in the current understanding of coagulopathy in COVID-19.

Regards,
Peter

-----Original Appointment-----

From: Adam, Stacey (FNIH) [T] [b6]

Sent: Thursday, April 30, 2020 7:55 AM

To: Adam, Stacey (FNIH) [T]; Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; Mellors, John W; Patel, Naimish /US; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E]

Cc: Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; [b6]
Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/NINDS) [E]

Subject: [EXTERNAL] ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #7

When: Tuesday, May 5, 2020 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: **b6**

EXTERNAL : Real sender is **b6**

Dear TX-Clinical Agent Prioritization Subgroup,

Please find attached the materials for today's meeting. My apologies for the late distribution.

Thanks,
Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/5/2020 11:14:47 PM
To: Eric Hughes [b6]; LaVange, Lisa M [b6]; Sandeep Menon [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Karen Lynn Price [b6]; Le Corre, Christophe [b6]; Ghosh, Pranab [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]
CC: Demarcus [b6]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #13 - Stats ONLY - HOLD

Location: [b6]

Start: 5/6/2020 3:00:00 PM

End: 5/6/2020 4:00:00 PM

Show Time As: Tentative

Required Attendees: Eric Hughes; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Karen Lynn Price; Le Corre, Christophe; Ghosh, Pranab; Read, Sarah (NIH/NIAID) [E]
Optional Attendees: Demarcus; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]

Dear TX-Clinical Master Protocol Subgroup Stats Group,

First, we have decided to limit this meeting just to this smaller group to really talk statistical design and simulation modeling. Second, due to some time conflicts for essential members of this group, we could not keep the meeting at 2-3pm, so right now it looks like we have the largest quorum for 11am-12pm ET tomorrow. We are moving the meeting to this time and holding it on everyone's calendar while we confirm all attendees availability.

Thanks,

Stacey

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From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 5/6/2020 1:28:28 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: RE: news and question

Yes! I spoke with Ruxandra, and they are indeed willing to shift the JnJ plans for infliximab, now preferring to have it included in ACTT-3 instead of going their own way. I was delighted. I'm looping in Stacey – does the WG need to re-confirm their 11.3 vote in order for this to be presented tomorrow, or can this be considered a done deal?

FC

From: Wholley, David (FNIH) [T] [b6]
Sent: Tuesday, May 5, 2020 8:55 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: RE: news and question

From what I hear it is likely good news. J&J is willing to put the trial they were planning for infliximab (Remicade), one of the immune modulators the Tx-Clinical Agent Prioritization Sub Group has put near the top of their list for ACTIV, on hold despite its being well through planning with FDA, in favor of putting it into the "ACTIV ACTT-3" protocol we are proposing to launch. She has discussed it with Mattai Mammen who makes these kinds of decisions. Don't know whether Paul Stoffels has been told yet. So what I strongly recommend you do: take the call, play dumb, and be absolutely delighted.

(Hope that is indeed what this turns out to be!)

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Tuesday, May 5, 2020 7:30 PM
To: Wholley, David (FNIH) [T] [b6]
Subject: FW: news and question
Importance: High

Any idea what this might be about?

From: Draghia Akli, Ruxandra [JRDUS] [b6]
Sent: Tuesday, May 5, 2020 6:14 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: news and question
Importance: High

Dear Francis – this world is getting smaller ☺ it is really great to be able to join forces on COVID. Another example of "all hands on deck" and undertaking something meaningful, with a tremendous impact on global health.

Would it be possible to have a short chat rapidly? I do have some news, and would like to get your feedback, if possible.

Kind regards, Rux

Ruxandra Draghia-Akli, MD, PhD

Global Head

Global Public Health R&D



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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/6/2020 2:35:42 AM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Colli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [b6]; Keith Gottesdiener [b6]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Elliott Levy [b6]; Sandeep Menon [b6]; Amanda Peppercorn [b6]; Proschan, Michael (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [b6]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [b6]; Wung, Peter /US [b6]; Karen Lynn Price [b6]; Pamela Tenaerts, M.D. [b6]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]
CC: Mary Biggs [b6]; Demarcus [b6]; Macone, Erin [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [b6]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]
Subject: Follow-up from ACTIV TX-Clinical Master Protocol Ad Hoc Meeting
Attachments: ACTIV_Therapeutics-Clinical_MP Sub-Group Meeting_Key Takeaways_05052020.pdf

Dear TX-Clinical Master Protocols Subgroup,

Please find attached the quick capture summary and action items from our meeting today. If you have any additions or amendments, don't hesitate to let us know.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/6/2020 2:41:38 AM
To: Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [b6]; Keith Gottesdiener [b6]; Elliott Levy [b6]; Wung, Peter /US [b6]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [b6]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: Follow-up from ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #7
Attachments: ACTIV_Therapeutics-Clinical_AP Sub-Group Meeting 7_Key Takeaways_05052020.pdf; 2020-05-03_TX-Clinical_WG_Agent_Prioritization_Subgroup_Summary-Amended.pdf

Dear TX-Clinical Agent Prioritization Subgroup,

Please find attached a quick summary of the action items and suggestions for improvement in the review process that Elizabeth was kind enough to capture for us today. While I will send out the official summary, I thought it might be beneficial for you all to have this today.

In addition, please find attached the modified summary from our final prioritization meeting for Wave 1 with additions from some of you captured.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health

APAR0000005487

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/6/2020 2:46:22 AM
To: Eric Hughes [b6]; LaVange, Lisa M [b6]; Sandeep Menon [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Karen Lynn Price [b6]; Le Corre, Christophe [b6]; Ghosh, Pranab [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]
CC: Demarcus [b6]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #13 - Stats ONLY

Attachments: ACTIV Therapeutics-Clinical_MP Subgroup_6May2020 Meeting Guide.pptx

Location: [b6]

Start: 5/6/2020 3:00:00 PM

End: 5/6/2020 4:00:00 PM

Show Time As: Tentative

Required Attendees: Eric Hughes; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Karen Lynn Price; Le Corre, Christophe; Ghosh, Pranab; Read, Sarah (NIH/NIAID) [E]
Optional Attendees: Demarcus; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]

Hi All,

Confirming this meeting and attaching just some slides that might help us tomorrow.

Thanks,

Stacey

Dear TX-Clinical Master Protocol Subgroup Stats Group,

First, we have decided to limit this meeting just to this smaller group to really talk statistical design and simulation modeling. Second, due to some time conflicts for essential members of this group, we could not keep the meeting at 2-3pm, so right now it looks like we have the largest quorum for 11am-12pm ET tomorrow. We are moving the meeting to this time and holding it on everyone's calendar while we confirm all attendees availability.

Thanks,

Stacey

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Sent: 5/6/2020 12:07:07 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [b6]; Eisner, Mark [b6]; Gottesdiener, Keith [b6]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; LaVange, Lisa [b6]; Levy, Elliot [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [b6]; Peppercorn, Amanda [b6]; Poole, Mike [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Amanda Peppercorn [b6]; Garner, Carl [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Kim, Elizabeth [elkim@deloitte.com]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Hughes, Eric [b6]
Subject: News from ACTIV Leadership

Dear TX-Clinical Working Group,

We wanted to let you know some news that was shared with us by the ACTIV Leadership Team.

In order to begin to show the field a unified plan and messaging for the testing of therapeutics for COVID-19 under ACTIV, the ACTIV Leadership has decided to bring into the program both the NIAID ACTT-2 Trial evaluating baricitinib and another NIAID master protocol evaluating IVIg and add these protocols to the portfolio of ACTIV Master Protocols. The ACTIV leadership is aware that our agent prioritization group think both the JAK/STAT inhibitors and IVIg are important to test, but knows we did not initially select them due to the development of these parallel trials. NIAID has already been working to ensure harmonization between these trials as we have with ACTT-3, so it was felt that these would be a natural fit to complement our efforts.

We are excited that our work is being recognized not only for ACTT-3, but also helping to promote further alignment and unity in the field.

Thank you all for all your efforts so far!

Sarah, Eric, and Stacey

Stacey J. Adam, PhD

Director, Cancer

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Sent: 5/6/2020 7:29:07 PM
To: Bascles, Lionel [b6]; Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [b6]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers, Betsy [b6]; Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshov, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshovj]; Garner, Carlos [b6]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Resnansky, Laura [b6]; Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Vincent, Mike [b6]; Wachtel, Jonathan [jwachtel@deloitte.com]
CC: Criffield, Robin [b6]; Hamilton, Nancy [b6]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Minnich, Beth [b6]; Mueller-Reichenstein, Petra [b6]; Quadros, Nora [b6]; Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Hill, Zoe (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [marganderson@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Carluccio, Dana [b6]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny [b6]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [b6]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveson, Nancy [b6]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [b6]; Jansen, Kathrin [b6]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [b6]

Subject: Summary and action items - CT Capacity WG meeting #5
Attachments: Clinical_Trial_Capacity_Working_Group_Meeting #6_Summary_Final.pdf

Dear Clinical Trial Capacity Working Group Members,

Attached is the summary and action items for meeting #6 (May 5, 2020) of the full working group. The next full working group meeting is scheduled for Friday, May 8 at 9 am eastern time USA.

Best regards,
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health

b6 fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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Sent: 5/6/2020 9:01:23 PM
To: Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [b6]; Keith Gottesdiener [b6]; Elliott Levy [b6]; Wung, Peter /US [b6]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [b6]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: 2nd Follow-up for ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #7
Attachments: 2020-05-05_TX-Clinical_WG_Agent_Prioritization_Committee_Meeting_Summary.pdf

Dear TX-Clinical Agent Prioritization Subgroup,

Please find attached the formal summary from yesterday's meeting. Please let me know if you have any additions or amendments.

Thanks,
Stacey

Stacey J. Adam, PhD
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Sent: 5/6/2020 9:35:12 PM
To: Eric Hughes [b6]; LaVange, Lisa M [b6]; Sandeep Menon [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Karen Lynn Price [b6]; Le Corre, Christophe [b6]; Ghosh, Pranab [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]
CC: Demarcus [b6]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Follow-up from ACTIV TX-Clinical Master Protocol Subgroup Meeting #13 - Stats ONLY
Attachments: ACTIV_Therapeutics-Clinical_MP Sub-Group Meeting 06May2020_Key Takeaways.pdf

Dear TX-Clinical Master Protocol Subgroup Stats Group,

Thank you all for a very productive meeting today. Please find attached the quick capture summary and action items that Elizabeth was kind enough to do for us. I look forward to us talking with the group on Friday and reconvening this group on Saturday.

Please let me know if you have time preferences for Saturday.

Thanks,

Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/7/2020 1:38:40 AM
To: Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [b6] Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [b6] Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [b6]; Keith Gottesdiener [b6]; Elliott Levy [b6]; Wung, Peter /US [b6]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [b6]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla [b6] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6] Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: Materials for ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #8
Attachments: ACTIV Therapeutics Clinical_Agent Prioritization Sub-Group Meeting 07May2020 Agenda.pdf; ACTIV Therapeutics-Clinical_AP Subgroup_7May2020 Meeting Guide.pdf

Dear TX-Clinical Agent Prioritization Subgroup,

We are looking forward to our meeting tomorrow during which we will work to flesh out some of our suggestions for improvements in the prioritization process a bit more. We will also talk about next steps over the rest of this week and next.

Please find attached the agenda and slides for tomorrow's meeting. If you have any additions or amendments, please let me know.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
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To: Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [b6]; Keith Gottesdiener [b6]; Elliott Levy [b6]; Wung, Peter /US [b6]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [b6]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]

CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bdfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]

Subject: ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #8

Attachments: ACTIV Therapeutics-Clinical_AP Subgroup_7May2020 Meeting Guide.pdf; ACTIV Therapeutics Clinical_Agent Prioritization Sub-Group Meeting 07May2020 Agenda.pdf

Location: [b6]

Start: 5/7/2020 5:00:00 PM

End: 5/7/2020 6:00:00 PM

Show Time As: Tentative

Required Attendees: Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E]

Optional Attendees: Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; [b6]; Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] [b6]

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Thanks,
Stacey

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Sent: 5/7/2020 2:11:25 AM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [b6]; Eisner, Mark [b6]; Gottesdiener, Keith [b6]; Hughes, Eric [b6]; Judy Carrier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [elkim@deloitte.com]; LaVange, Lisa [b6]; Levy, Elliot [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [b6]; Peppercorn, Amanda [b6]; Poole, Mike [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coll]; Amanda Peppercorn [b6]; Garner, Carl [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]
CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [b6]; Jansen, Kathrin [b6]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [b6]; Biggs, Mary [b6]; Butcher, Tina [b6]; Demarcus [b6]; Macone, Erin [b6]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan [jwachtel@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Alvarez, Rosa [rosalvarez@deloitte.com];

Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Anderson, Margaret [marganderson@deloitte.com]; Lucas Smalldon [b6]; Stratton, Benjamin [bstratton@DELOITTE.com]; jennifer.j.palmer@pfizer.com; Mollica, Linda /US [b6] Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]

Subject: Material for ACTIV TX-Clinical Working Group #5

Attachments: ACTIV Therapeutics-Clinical WG 7May2020 Meeting Guide.pdf; ACTIV Therapeutics-Clinical WG 7May2020 Agenda.pdf

Dear TX-Clinical Working Group and Invite Guests,

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Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

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Subject: ACTIV TX-Clinical Working Group #5

Attachments: ACTIV Therapeutics-Clinical WG 7May2020 Meeting Guide.pdf; ACTIV Therapeutics-Clinical WG 7May2020 Agenda.pdf

Location: [b6]

Start: 5/7/2020 6:00:00 PM

End: 5/7/2020 7:00:00 PM

Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]

Optional Attendees: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; [b6]; Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]

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CC: Tolman, Brett [btolman@deloitte.com]; Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; [b6] [b6] Johnson, Maureen (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr]; Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; [b6] [b6] Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Douoguih, Macaya [JRDUS] [b6] Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Gilbert PhD, Peter B [b6] Paul Gillard [b6]; Gruber, Marion (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ebf7a8eb8dd541b2883a966ea5afd809-GRUBER.fda]; Gurunathan, Sanjay /US [b6] Hamilton, Holli (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a28cf2f8eb134b00b5eaa4222d0576cc-Holli.Hamil]; [b6] Ledgerwood, Julie (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5dc9f31ded594eff8ac506d2c4103c15-ledgerwood]; Leyssen, Maarten [JRDNL] [b6] Marovich, Mary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bfd0192d165d4643accf6347728dbaeb-marovichma]; Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33958e1252cf4266bffc8d94988f5715-kneuzil.com]; Robb, Merlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17bbdb1e858542e7b5959ec7aeb7679a-mrobb.hivre]; [b6] Michael Watson (x) [b6] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; [b6] Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Read, Sarah (NIH/NIAID) [E]

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Subject: REVIEW REQUESTED: Covid-19 human challenge model perspective outline; also Vaccines WG meeting notes

Attachments: SARS-CoV-2 Controlled Human Infection Model in Support of Preventive Vaccines Outline.docx; controlled human infection model references.zip; 2020-05-05 Working Group meeting Summary Notes.docx

Dear Vaccines Working Group (and cc'ing other Sub-Group members),

Thank you for your participation in yesterday's Vaccines Working Group meeting. Summary notes kindly prepared by the science writer that supports our group are attached. If you have any additions or edits, please feel free to pass them along.

As we discussed at the meeting, an important new deliverable for our Working Group is a perspective on the scientific and operational obstacles for developing a COVID-19 human challenge model on a relevant timescale. A small team from the Vaccine Clinical Trials Sub-Group has taken on that responsibility, with our gratitude.

Please review the attached outline. The team has a particular question about how much substantiation of the points being made is necessary. The team is also contemplating which audiences to target and the best ways to reach them. **If you have suggestions or feedback on the outline, or perspectives on these questions, please share them with us.** Existing papers on this topic are attached in the zip file for your reference. This will be an important agenda topic at our next Working Group meeting on Monday, May 11, 12pm ET (9am PT / 6pm CEST).

We look forward to continued engagement as we forge ahead on the path to support accelerated vaccine development. Please reach out anytime with questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]

Sent: Tuesday, May 5, 2020 2:44 AM

Subject: Agenda and Materials for ACTIV Vaccines Working Group meeting: Today, 5 May

Dear Vaccines Working Group,

We are looking forward to our next Vaccines Working Group meeting with you, today (Tuesday) at 12pm ET (9am PT / 6pm CEST). The key agenda items for our meeting are:

- Review new mandates for the Working Group
- Discuss pathways to approval/authorization using correlates and other evidence
- Share ACTIV external communications approach

The slides that we will use during the meeting are attached, with some additional slides drawn from the presentation Marion Gruber shared (attached in full in Friday's notes) in an appendix for reference.

We also want to share an update related to the first agenda item. The Vaccines Clinical Trials Sub-Group met for the first time yesterday (Monday). Much as we anticipate the master protocol trial doing, we rapidly enrolled participants (though perhaps with limited informed consent) in this Sub-Group; the roster as of today is attached, with some additional invitations pending. We have also attached the notes from that meeting.

As always, please do not hesitate to reach out with any input or questions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Sunday, May 3, 2020 5:45 PM
Subject: Vaccines Working Group important update: Clinical Trial plans

Dear Vaccines Working Group,

Yesterday evening there was an exciting expansion of the opportunity for the Vaccines Working Group to contribute to accelerating vaccine development. We learned that there will be US government funding for a master protocol phase 2/3 adaptive vaccine efficacy trial, with provisions to add and drop vaccine candidate arms over time.

The Clinical Trial Sub-Group (slight name change) will be tasked with supporting this master protocol trial, including the protocol and the networks/sites implementation. The goal is to have this trial ready to start by July 1, though there may be an opportunity to start in June if the work can be completed by then.

This is a significant expansion of scope for the Sub-Group. Given the magnitude of this responsibility, we will be asking for additional representation on the Sub-Group and pulling in expertise, including some of the master protocols experts that have been writing the ACTIV therapeutics protocols. The first meeting of the Sub-Group is tomorrow at 10am ET (7am PT / 4pm CEST).

We will also discuss this at the Vaccines Working Group meeting on Tuesday at 12pm ET (9am PT / 6pm CEST). Please don't hesitate to reach out with any questions.

Best regards,
Mike, for the Vaccines Working Group

Michael Santos, PhD
Associate Vice President, Science
Foundation for the National Institutes of Health

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Subject: ACTIV TX-Clinical Master Protocol Subgroup #15
Location: [b6]
Start: 5/11/2020 5:00:00 PM
End: 5/11/2020 6:00:00 PM
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Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butters; Collins, Sylvia (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Scott Berry; Angus, Derek; Meredith Buxton; Patterson, Amy (NIH/NHLBI) [E]

Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Goffney, Robertta

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CC:

Subject: ACTIV TX-Clinical Master Protocol Subgroup #15

Attachments: ACTIV Therapeutics-Clinical_MP Subgroup_11May2020 Meeting Guide.pdf; Adapt Out COVID Overview051120.pdf

Location: [b6]

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Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Eron, Joseph J Jr; Javan, Arzhang (NIH/NIAID) [E]

Dear TX-Clinical Master Protocol Subgroup,

Please find attached the materials for today's call. We will be discussing the statistical simulations the group has put together for ACTT-3, as well as we will have a presentation from the ACTG group on their outpatient master protocol.

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Thanks,
Stacey

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Subject: ACTIV TX-Clinical Agent Prioritization Subgroup #9
Location: [b6]
Start: 5/12/2020 5:00:00 PM
End: 5/12/2020 6:00:00 PM
Show Time As: Tentative

Required Attendees: Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E]
Optional Attendees: Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; [b6]; Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] [b6]

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/7/2020 8:56:23 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Ruxandra Draghia-Akli [b6]; Mellors, John W [b6]; Naimish Patel [b6]; Colvis, Christine (NIH/NCATS) [E] [b6]; Young, John [b6]; Stein, Peter (FDA/CDER) [b6]; Poole, Mike [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [b6]; Vincent, Michael [b6]; Keith Gottesdiener [b6]; Elliott Levy [b6]; Wung, Peter /US [b6]; Koroshetz, Walter (NIH/NINDS) [E] [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6]; Carlos O Garner [b6]; Goff, David (NIH/NHLBI) [E] [b6]
CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [b6]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [dwholley@fnih.org]; Melencio, Cheryl (FNIH) [T] [b6]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [b6]; Ward, Jackie (NIH/NINDS) [E] [b6]
Subject: ACTIV TX-Clinical Agent Prioritization Subgroup #9
Location: [b6]
Start: 5/12/2020 5:00:00 PM
End: 5/12/2020 6:00:00 PM
Show Time As: Busy

Required Attendees: Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E]
Optional Attendees: Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; [b6]; Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] [b6]

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/7/2020 8:58:52 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [b6]; Keith Gottesdiener [b6]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Elliott Levy [b6]; Sandeep Menon [b6]; Amanda Peppercorn [b6]; Proschan, Michael (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [b6]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [b6]; Wung, Peter /US [b6]; Karen Lynn Price [b6]; Pamela Tenaerts, M.D. [b6]; Scott Berry [b6]; Angus, Derek [b6]; Meredith Buxton [b6]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]
CC: Mary Biggs [b6]; Demarcus [b6]; Macone, Erin [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [b6]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Goffney, Robertta [b6]
Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #16
Location: [b6]
Start: 5/13/2020 5:00:00 PM
End: 5/13/2020 6:00:00 PM
Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butters; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Scott Berry; Angus, Derek; Meredith Buxton; Patterson, Amy (NIH/NHLBI) [E]

Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Goffeney, Robertta

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/7/2020 8:58:53 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E]; [b6] Butterson, Joan [b6] Collins, Sylva (FDA/CDER) [b6]; Judy Currier [b6]; De Claro, R. Angelo (FDA/CDER) [b6]; Mark Eisner [b6]; Keith Gottesdiener [b6]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Elliott Levy [b6]; Sandeep Menon [b6]; Amanda Peppercorn [b6]; Proschan, Michael (NIH/NIAID) [E]; [b6]; Read, Sarah (NIH/NIAID) [E]; [b6]; Amanda Peppercorn [b6]; Price, Dionne (FDA/CDER); [b6]; Rubin, Daniel B. (FDA/CDER); [b6]; Shen, Yuan Li (FDA/CDER); [b6]; Farley, John (FDA/CDER); [b6]; Vincent, Michael [b6]; Wung, Peter /US [b6]; Karen Lynn Price [b6]; Pamela Tenaerts, M.D.; [b6]; Patterson, Amy (NIH/NHLBI) [E]; [b6]; Esserman, Laura [b6]; Higgs, Elizabeth (NIH/NIAID) [E]; [b6]; James Palazzolo [b6]; Burgess, Timothy [b6]; Beumont-Mauviel, Maria [JRDUS]; [b6]; Peeters, Monika [JRDBE]; [b6]; Woodfall, Brian [JRDUS]; [b6]; Van Heeswijk, Rolf [JRDBE]; [b6]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Mary Biggs [b6]; Demarcus [b6]; Macone, Erin [b6]; Tountas, Karen (FNIH) [T]; [b6]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [b6]; Wholley, David (FNIH) [T]; [b6]; Melencio, Cheryl (FNIH) [T]; [b6]; Forster, Katherine [b6]
Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #16
Location: [b6]
Start: 5/13/2020 5:00:00 PM
End: 5/13/2020 6:00:00 PM
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Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Patterson, Amy (NIH/NHLBI) [E]; Esserman, Laura; Higgs, Elizabeth (NIH/NIAID) [E]; James Palazzolo; Burgess, Timothy; Beumont-Mauviel, Maria [JRDUS]; Peeters, Monika [JRDBE]; Woodfall, Brian [JRDUS]; Van Heeswijk, Rolf [JRDBE]
Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Forster, Katherine

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
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CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla [b6] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bafd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]

Subject: ACTIV TX-Clinical Agent Prioritization Subgroup #10

Location: [b6]

Start: 5/14/2020 5:00:00 PM

End: 5/14/2020 6:00:00 PM

Show Time As: Tentative

Required Attendees: Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E]

Optional Attendees: Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; [b6] Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] [b6]

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]

Sent: 5/7/2020 9:04:22 PM

To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Ruxandra Draghia-Akli [b6]; Mellors, John W [b6]; Naimish Patel [b6]; Colvis, Christine (NIH/NCATS) [E] [b6]; Young, John [b6]; Stein, Peter (FDA/CDER) [b6]; Poole, Mike [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [b6]; Vincent, Michael [b6]; Keith Gottesdiener [b6]; Elliott Levy [b6]; Wung, Peter /US [Peter.Wung@sanofi.com]; Koroshetz, Walter (NIH/NINDS) [E] [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6]; Carlos O Garner [b6]; Goff, David (NIH/NHLBI) [E] [b6]

CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [b6]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [b6]; Ward, Jackie (NIH/NINDS) [E] [b6]; Dana Carluccio [b6]; Rose Li Central Account [FNIH@roseliassociates.com]

Subject: ACTIV TX-Clinical Agent Prioritization Subgroup #10

Attachments: IL-6 Trial Information.pdf; ACTIV_Therapeutics Clinical Agent Prioritization Sub Group_14May2020 Meeting Guide.pdf; Therapeutic information request form-v4.docx

Location: [b6]

Start: 5/14/2020 5:00:00 PM

End: 5/14/2020 6:00:00 PM

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Required Attendees: Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E]

Optional Attendees: Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; [b6]; Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] [b6]; Dana Carluccio; Rose Li Central Account

Dear ACTIV TX-Clinical Agent Prioritization Subgroup,

Please find attached the materials for tomorrow's call. We will use them to follow up on our conversations from Tuesday, and well as discuss next steps.

The materials include:

1. Meeting slides for tomorrow, which have both the updated Agent Prioritization Criteria and Weighted Scoring Rubric for your review. **Please take a look and see if Elizabeth and I captured all your thoughts from Tuesday.**
2. Slides with Status of IL-6 trials for three agents in the clinic. **Please take a look at these slides and see if this is the type of snapshot information you have wanted to be able to pull for any given agent as you review.** While I know there is some desirable information missing, such as RCT vs. uncontrolled trial, if it looks good, feel free to play around a bit more with the tracker from Oxford that I pulled the data from: http://covid19.trialstracker.net/data_viz.html. What I am hoping to understand is if there are publicly available sites that can help fill our data aggregation needs until we can potentially get access to others that maybe more

comprehensive. For comparison to the Oxford site, you can check out the Cytel site which maps the trials to given countries, but only shows intended accrual and not current accrual like the Oxford site: <https://covid19-trials.com/>. The challenge is likely that we may need a couple sites to fulfill the information that we need, but it would prevent us from reinventing the wheel that other maybe creating already. I will continue exploring options, but thanks for reviewing.

3. Finally, as discussed on Tuesday, the preclinical group and our team have worked to put together a first version of the company survey/RFI that we would use for multiple purposes: 1) to do specific information solicitation on high priority compounds that this group wishes to score, 2) to have any company or group who has submitted an agent for your consideration populate this so we are working on the right data, and 3) potentially to do a broad company solicitation of additional compounds that the companies would like to have considered for testing.

Please review and let us know if this has all the questions you would want to see to ensure that we will have the right data to review for our high priority compounds. We have worked to balance being thorough with making sure it is not too onerous for a company to fill out. **Please let us know if you have any amendments or additions.**

Thank you for your review of these materials. We look forward to a productive call tomorrow.

Thanks,
Stacey

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CC: Mary Biggs [b6]; Demarcus [b6]; Macone, Erin [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [b6]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Goffney, Robertta [b6]
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Location: [b6]
Start: 5/15/2020 5:00:00 PM
End: 5/15/2020 6:00:00 PM
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Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Scott Berry; Angus, Derek; Meredith Buxton; Patterson, Amy (NIH/NHLBI) [E]

Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Goffeney, Robertta

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CC: [b6]; Demarcus [b6]; Macone, Erin [b6]; Tountas, Karen (FNIH) [T] [ktountas@fnih.org]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina [b6]; Wholley, David (FNIH) [T]; [b6]; Melencio, Cheryl (FNIH) [T]
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Attachments: ACTIV Therapeutics-Clinical_MP Subgroup_15May2020 Meeting Guide.pdf
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Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]

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Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Anderson, Margaret [marganderson@deloitte.com]; Lucas Smalldon [b6]; Stratton, Benjamin [bstratton@DELOITTE.com]; [b6] Mollica, Linda /US [b6] Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]

Subject: ACTIV TX-Clinical Working Group #6

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Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]

Optional Attendees: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; [b6] Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]

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CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [b6]; Jansen, Kathrin [b6]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [b6]; Biggs, Mary [b6]; Butcher, Tina [b6]; Demarcus [b6]; Macone, Erin [b6]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan [jwachtel@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Alvarez, Rosa [rosalvarez@deloitte.com]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Anderson, Margaret [marganderson@deloitte.com]; Lucas Smalldon [b6]; Stratton, Benjamin [bstratton@DELOITTE.com]; [b6] Mollica, Linda /US [b6] Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]

Subject: ACTIV TX-Clinical Working Group #6

Attachments: FDA Guidance on COVID Trials.pdf; ACTIV Therapeutics-Clinical Full Working Group_14May2020 Meeting Guide.pdf

Location: [b6]

Start: 5/14/2020 6:00:00 PM

End: 5/14/2020 7:00:00 PM

Show Time As: Busy

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]

Optional Attendees: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; [b6] Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; [b6]

Dear TX-Clinical Working Group,

Please find attached the slides for tomorrow's call to help facilitate our report outs from both groups. If you have any additions or amendments to propose, please send them to me.

The co-chairs will be updating the group on the ACTIV Executive Committee's feedback and promised actions in response to our letter. This will include some immediate next steps for our group on the mAbs master protocol discussion. Thank you all once again for this feedback to the leadership. It was well received, and it looks like will elicit immediate action on some of the requests.

In addition, please find attached the FDA Guidance for COVID-19 trials that was released today. You can also find it at this link if needed: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/covid-19-developing-drugs-and-biological-products-treatment-or-prevention>

Looking forward to tomorrow’s call.

Thanks,
Stacey

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To: Vincent, Mike [b6]; Bascles, Lionel [b6]; Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [b6]; Desrosiers, Betsy [b6]; Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshow, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshoj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; King, James (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce1f3853e43d4463a04f7d74992f96ac-James.King.]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura [b6]; Srinivasan, Badhri [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wachtel, Jonathan [jwachtel@deloitte.com]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]
CC: Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Kenny, Dermot [b6]; Garner, Carlos [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [b6]; Jansen, Kathrin [b6]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [b6]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [marganderson@deloitte.com]; Carluccio, Dana [b6]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny [b6]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [b6]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a27ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveson, Nancy [b6]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Criffield, Robin [b6]; Hamilton, Nancy [b6]; Minnich, Beth

[b6]; Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Stratton, Benjamin [bstratton@DELOITTE.com]; Tolman, Brett [btolman@deloitte.com]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Jintanat Ananworanich; [b6]

Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting

Attachments: ACTIV Partnership Leadership Team Meeting 20200506 FINAL CTC WG slides.pdf; Clinical Trial Capacity Working Group Meeting Agenda_05072020.pdf

Location: [b6]

Start: 5/8/2020 1:00:00 PM

End: 5/8/2020 2:00:00 PM

Show Time As: Tentative

Recurrence: Weekly
every Tuesday and Friday from 9:00 AM to 10:00 AM

Required Attendees: Vincent, Mike; Bascles, Lionel; Cohen, Myron; Corey, Larry; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshov, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; King, James; Kurilla, Mike; Nayak, Seema (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Payton, Manzine; Resnansky, Laura; Srinivasan, Badhri; Stein, Peter (FDA/CDER); Wachtel, Jonathan; Woodcock, Janet (FDA/CDER); Qashu, Felicia

Optional Attendees: Sizemore, Christine (NIH/FIC) [E]; Kenny, Dermot; Garner, Carlos; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Carluccio, Dana; Cheryl (FNIH) Melencio [T] ([b6] Francis Collins; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH); Tuveson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Minnich, Beth; Rebecca (NIH/NCATS) Katz [E] [b6] Thomas, Ashley (FDA/CDER); Stratton, Benjamin; Tolman, Brett; Davey, Victoria; Jintanat Ananworanich

Dear Colleagues – Attached is the meeting agenda along with slides that the WG co-chairs, Betsy Desrosiers and Mike Kurilla, presented to the ACTIV Leadership on Wednesday. Best, Karen

ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines

Dear Clinical Trial Capacity Working Group members,

In anticipation of this working group making rapid progress on identified action items and other activities, the co-chairs have agreed that it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify areas of need, and to determine next steps. We ask that you make every effort possible to join each of these meetings, but understand that at times you may have competing priorities. To place a hold on your calendar, please accept this meeting invite with a response; later you can decline an individual meeting if you have a conflict.

An agenda and other meeting materials, as needed, will be distributed prior to each call.

With best regards,
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health

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CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla [b6] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6] Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: RE: ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #8

Dear TX-Clinical Agent Prioritization Subgroup,

Please find below the action items from today's meeting. Keith has already been kind enough to follow up on his and let us know that Allergan does not have another study planned at this time.

As for the other Sarah, Eric, Elizabeth, and I will begin working on a strawman for this team's review next week.

Thanks,
Stacey

Action Items		
Information		POC
1	Learn whether CCR5 cenicriviroc is planned to go into another trial	Keith Gottesdiener
2	Amend/create materials needed for revised scoring process	Sarah Read, Eric Hughes, Stacey Adam, Elizabeth Kim

Stacey J. Adam, PhD

Director, Cancer

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/8/2020 2:20:33 AM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Colli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [b6]; Keith Gottesdiener [b6]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Elliott Levy [b6]; Sandeep Menon [b6]; Amanda Peppercorn [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [b6]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [b6]; Wung, Peter /US [b6]; Karen Lynn Price [b6]; Pamela Tenaerts, M.D. [b6]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]
CC: Mary Biggs [b6]; Demarcus [b6]; Macone, Erin [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [b6]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Material for ACTIV TX-Clinical Therapeutics Master Protocol Subgroup Meeting #14
Attachments: ACTIV Therapeutics-Clinical_MP Subgroup_8May2020 Meeting Guide.pdf; ACTIV Therapeutics Clinical MP Sub Group 8May2020_Meeting Agenda.pdf

Dear ACTIV TX-Clinical Therapeutics Master Protocol Subgroup,

Please find attached the agenda and slides for our portion of the meeting tomorrow. As you will note, the first half of the call will be the REMAP-COVID team presenting to our group.

Thanks,
Stacey

APAR0000005460

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/8/2020 2:20:43 AM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Colli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [b6]; Keith Gottesdiener [b6]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Elliott Levy [b6]; Sandeep Menon [b6]; Amanda Peppercorn [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [b6]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [b6]; Wung, Peter /US [b6]; Karen Lynn Price [b6]; Pamela Tenaerts, M.D. [b6]; Scott Berry [b6]; Angus, Derek [b6]; Meredith Buxton [b6]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]
CC: Mary Biggs [b6]; Demarcus [b6]; Macone, Erin [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina [b6]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Goffeney, Robertta [b6]
Subject: ACTIV TX-Clinical Therapeutics Master Protocol Subgroup #14
Attachments: ACTIV Therapeutics Clinical MP Sub Group 8May2020_Meeting Agenda.pdf
Location: [b6]
Start: 5/8/2020 5:00:00 PM
End: 5/8/2020 6:00:00 PM
Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butters; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Scott Berry; Angus, Derek; Meredith Buxton; Patterson, Amy (NIH/NHLBI) [E]

Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Goffeney, Robertta

Dear ACTIV TX-Clinical Therapeutics Master Protocol Subgroup and Invited Guests,

Please find attached the agenda for our portion of the meeting tomorrow. As you will note, the first half of the call will be the REMAP-COVID team presenting to our group. We are looking forward to hearing more about their efforts.

Thanks,
Stacey

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From: Read, Sarah (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=527B160038004A199AE6E0BAC2226099-READSA]
Sent: 5/8/2020 3:07:23 PM
To: Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: RE: ACTIV antivirals

Yes, that is correct Walter. Our plan is to have closer coordination with the ACTIV preclinical group as well as Gates with Mike Poole in our group for future rounds of prioritization to make sure we have the most reliable data available.

Sarah

From: Koroshetz, Walter (NIH/NINDS) [E] [b6]
Sent: Friday, May 8, 2020 10:40 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Read, Sarah (NIH/NIAID) [E]
Subject: ACTIV antivirals

Dear Francis

Sarah can correct me, but our ACTIV group was not confident about the potency claims of the different antivirals. For some compounds there were disparate reports, off by factor of 10 or more. I think this is the major reason we did not put an anti-viral forward in the first go around.

We understand that there are at least two standardized assay systems set up to compare 100's of antivirals (I thought Gates foundation in Leuven and another in US). We are hoping that this will give data in that would enable us to choose among the many. Just need to ensure that the ones that come to us can be tested in these standardized assays.

Walter

Walter J. Koroshetz, M.D.
Director, National Institute of Neurological Disorders and Stroke

From: Wachtel, Jonathan [jwachtel@DELOITTE.com]
Sent: 5/8/2020 3:11:02 PM
To: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Vincent, Mike [b6]; Bascles, Lionel [b6] Cohen, Myron [b6] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [b6] Desrosiers, Betsy [elizabeth_desrosiers@merck.com]; Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshov, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshovj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; King, James (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce1f3853e43d4463a04f7d74992f96ac-James.King.]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura [b6]; Srinivasan, Badhri [b6] Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]
CC: Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Kenny, Dermot [b6]; Garner, Carlos [b6] Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [b6]; Jansen, Kathrin [b6] Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [b6]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [marganderson@deloitte.com]; Carluccio, Dana [b6] Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny [b6] James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [b6]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveson, Nancy [b6] Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Criffield, Robin

[b6] Hamilton, Nancy [b6]; Minnich, Beth [bminnich@fredhutch.org]; Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Stratton, Benjamin [bstratton@DELOITTE.com]; Tolman, Brett [btolman@deloitte.com]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Jintanat Ananworanich [b6]

Subject: RE: ACTIV Clinical Trial Capacity Working Group - reporting meeting

Attachments: Network Inventory Master Spreadsheet 05082020.xlsx

CTC WG Members-

Please find the most current Network Inventory spreadsheet. If you look at the bottom rows on the tab titled 'Other' you will see both the CROs and SMOs we are currently tracking. **Let me know if you have others to add to this list – please include contact info as well.**

Laura/Betsy – can you send me the POC/email for the following CROs, even though you will send direct to your contacts. I don't have them in my tracker.

- ICON
- PRA
- SYNEOS
- Parexel

THANKS!!

Jonathan Wachtel
Deloitte Consulting LLP
Tel/Direct: +1 301 275 8249
www.deloitte.com

-----Original Appointment-----

From: Tountas, Karen (FNIH) [T] [b6]

Sent: Tuesday, April 14, 2020 6:40 PM

To: Tountas, Karen (FNIH) [T]; Vincent, Mike; Bascles, Lionel; Cohen, Myron; Corey, Larry; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshov, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; King, James (OS/ASPR/BARDA); Kurilla, Michael (NIH/NCATS) [E]; Nayak, Seema (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Payton, Manizhe (NIH/NIAID) [E]; Resnansky, Laura; Srinivasan, Badhri; Stein, Peter (FDA/CDER); Wachtel, Jonathan; Woodcock, Janet (FDA/CDER); Qashu, Felicia (NIH/OD) [E]

Cc: Sizemore, Christine (NIH/FIC) [E]; Kenny, Dermot; Garner, Carlos; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Carluccio, Dana; Melencio, Cheryl (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Gonzalez, Nina; Heaton, Penny; James, Stephanie (FNIH) [T]; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Tuveson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Minnich, Beth; Katz, Rebecca (NIH/NCATS) [E]; Thomas, Ashley (FDA/CDER); Stratton, Benjamin; Tolman, Brett; Victoria Davey; Jintanat Ananworanich

Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting

When: Friday, May 8, 2020 9:00 AM-10:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: [b6]

Dear Colleagues – Attached is the meeting agenda along with slides that the WG co-chairs, Betsy Desrosiers and Mike Kurilla, presented to the ACTIV Leadership on Wednesday. Best, Karen

ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines

Dear Clinical Trial Capacity Working Group members,

In anticipation of this working group making rapid progress on identified action items and other activities, the co-chairs have agreed that it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify areas of need, and to determine next steps. We ask that you make every effort possible to join each of these meetings, but understand that at times you may have competing priorities. To place a hold on your calendar, please accept this meeting invite with a response; later you can decline an individual meeting if you have a conflict.

An agenda and other meeting materials, as needed, will be distributed prior to each call.

With best regards,
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health

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From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
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To: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Bascles, Lionel
[b6]; Cohen, Myron [b6]; Corey, Larry [b6]
Victoria Davey [b6]; Desrosiers, Betsy [b6]; Dickens, Jim (NIH/NCATS) [C]; [b6]; Doroshow, James (NIH/NCI) [E]; [b6]; Garner, Carlos [b6]; Goff, David (NIH/NHLBI) [E]; [b6]; Kurilla, Michael (NIH/NCATS) [E]
[b6]; Nayak, Seema (NIH/NIAID) [E]; [b6]; Payton, Manizhe (NIH/NIAID) [E]
[b6]; Qashu, Felicia (NIH/OD) [E]; [b6]; Resnansky, Laura [b6]; Sizemore, Christine (NIH/FIC) [E]; [b6]; Srinivasan, Badhri [b6]; Stein, Peter (FDA/CDER) [b6]; Vincent, Mike [b6]; Wachtel, Jonathan [jwachtel@deloitte.com]; Mensah, George (NIH/NHLBI) [E]
[b6]; Weinmann, Gail (NIH/NHLBI) [E]; [b6]
CC: Criffield, Robin [b6]; Hamilton, Nancy [b6]; Melencio, Cheryl (FNIH) [T]; [b6]; Minnich, Beth [b6]; Mueller-Reichenstein, Petra [b6]; Quadros, Nora [b6]; Katz, Rebecca (NIH/NCATS) [E]; [b6]; Hill, Zoe (NIH/NHLBI) [C]; [b6]; Adam, Stacey (FNIH) [T]; [b6]
Anderson, Margaret [marganderson@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Carluccio, Dana; [b6]; Gonzalez, Nina [ningonzalez@deloitte.com]; Heaton, Penny [b6]; James, Stephanie (FNIH) [T]; [b6]; Li, Rose [b6]; Menetski, Joseph (FNIH) [T]; [b6]; Santos, Michael (FNIH) [T]
[b6]; Tuveson, Nancy [b6]; [b6]; Wholley, David (FNIH) [T]
[b6]; Colvis, Christine (NIH/NCATS) [E]; [b6]; Hughes, Eric [b6]; Jansen, Kathrin [b6]; Lowy, Douglas (NCI) [b6]
Read, Sarah (NIH/NIAID) [E]; [b6]; Young, John [b6]
Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting
Attachments: Untitled Attachment; Untitled Attachment
Location: [b6]
Start: 5/26/2020 1:00:00 PM
End: 5/26/2020 2:00:00 PM
Show Time As: Busy
Recurrence: Weekly
every Tuesday and Friday from 9:00 AM to 10:00 AM
Required Attendees: Bascles, Lionel; Cohen, Myron; Corey, Larry; Davey, Victoria; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshow, James (NIH/NCI) [E]; Garner, Carlos; Goff, David (NIH/NHLBI) [E]; Kurilla, Mike; Nayak, Seema (NIH/NIAID) [E]; Payton, Manizhe; Qashu, Felicia; Resnansky, Laura; Sizemore, Christine (NIH/FIC) [E]; Srinivasan, Badhri; Stein, Peter (FDA/CDER); Vincent, Mike; Wachtel, Jonathan
Optional Attendees: Criffield, Robin; Hamilton, Nancy; Melencio, Cheryl (FNIH) [T]; Minnich, Beth; Mueller-Reichenstein, Petra; Quadros, Nora; Rebecca (NIH/NCATS) Katz [E]; [b6]; Zoe (NIH/NHLBI) Hill [C]; [b6]; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Ashley (NIH/OD) Parker [E]; [b6]; Carluccio, Dana; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH); Tuveson, Nancy; Wholley, David (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John

Dear Clinical Trial Capacity WG members, This will extend our full working group calls through the end of May. We'll assess the need for further meetings at the end of the month. Many thanks for your participation! Karen

Join Zoom Meeting

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From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 5/8/2020 8:00:21 PM
To:

b6

b6 Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
b6 Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
b6 Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas /US
b6 Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; **b6**
b6
CC: Diamond, Michael **b6** Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy
b6 Hughes, Eric **b6** Jansen, Kathrin
b6 Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Kim, Elizabeth [elkim@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Wachtel, Jonathan [jwachtel@deloitte.com]; Prabhavathi Fernandes **b6**; Rose Li
b6 Dana Carluccio **b6** Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Jonson, Samantha

(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [b6] Dave Frankowski [b6]

Subject: May 8 ACTIV Preclinical working group ACTION ITEMS

Attachments: ACTIV PRECLINICAL_Animal Model Inventory_20200507.xlsx; Antiviral expert names.docx; Small animal models d1 MD.pptx

Dear Preclinical Working Group attendees,

Thank you for an interesting a productive meeting today. It really is a pleasure working with you.

We are working on the minutes, but I wanted to distribute the action items so that you can get started on the items that need your input.

1. Joe and Rosa to send the animal model inventory excel file to the Preclinical working group and to the leads of the Vaccine working group to review. Specific request: ensure that the all columns needed for prioritization and analysis are captured. (It is easier to take columns away versus adding them after we begin collecting data)
2. The Preclinical WG is asked to provide any concerns about proposed members of the in vitro expert panel to Joe by this evening (Saturday afternoon at the latest). If no objections, then Joe will send a letter of invitation to join the ACTIV expert panel and begin to setup an initial meeting.
3. Michael Diamond will draft a 1-2 page preclinical asset review sheet (for expert panel review) before the end of the weekend. Joe will send the draft to the Preclinical WG to provide additions from the animal model working group as well as anyone in the WG. This initial in vitro/ in vivo preclinical asset review sheet will be used as a starting point for the expert panels to modify. We will use this to begin setting up an input form for the needed data by potential sponsors.
4. Industry members of the working group will suggest people with CRO or industry experience but currently non-conflicted positions to the in vivo expert panel. These will be added to the NIH and academic suggestions by Dr Jim Anderson.
5. Jim Anderson and Chris Austin will work to obtain a view into all the NIH data in the publication portal supported by the office of portfolio management.
6. Joe will share the slide from Mike Diamond on the cross subgroup information.

Best regards,

Joe and Rosa

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T]

Sent: Tuesday, April 14, 2020 6:48 PM

To: [b6] Menetski, Joseph (FNIH) [T];

b6

b6

[b6] Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas /US; Anderson, James (NIH/OD) [E]

Cc: Diamond, Michael; Florence, Clint (NIH/NIAID) [E]; Wholley, David (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Lowy,

Douglas (NIH/NCI) [E]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; **b6**

Subject: ACTIV Preclinical working group (Friday meeting)

When: Friday, May 8, 2020 11:00 AM-12:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: **b6**

Holding time

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 5/9/2020 1:17:56 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
Subject: RE: do we need an Executive Committee meeting with the co-chairs sooner rather than later?
Attachments: ACTIV Executive Committee; ACTIV Executive Committee (ADMINS); ACTIV Working Group Co-chairs

Dear Dr. Collins:

Attached are the distribution lists for the Executive Committee and the Co-chairs. I have also listed them below.

Executive Committee:

Collins, Francis (NIH/OD) [E] [b6] Fauci, Anthony (NIH/NIAID) [E] [b6]; Gibbons, Gary (NIH/NHLBI) [E] [b6]; Stoffels, Paul [b6]; Wood, Gretchen (NIH/OD) [E] [b6] Pao, William [b6]; Dolsten, Mikael [b6]

Co-chairs

Colvis, Christine (NIH/NCATS) [E] [b6]; Desrosiers, Betsy [b6]; Hughes, Eric [b6]; Jansen, Kathrin [b6]; Kurilla, Michael (NIH/NCATS) [E] [b6]; Lowy, Douglas (NCI) [b6]; Read, Sarah (NIH/NIAID) [E] [b6] Young, John [b6]

Let me know if you need anything else.

Cheryl

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health
[b6]

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From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Friday, May 8, 2020 7:32 PM
To: Wholley, David (FNIH) [T] [b6]
Cc: Melencio, Cheryl (FNIH) [T] [b6]; Wood, Gretchen (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Subject: RE: do we need an Executive Committee meeting with the co-chairs sooner rather than later?

Thanks for drafting this. I've made a few edits. Can Cheryl send me the e-mail list for the co-chairs and the Exec Comm?

I don't think I have seen the letter from the Clinical Therapeutics WG. Is there some chance this invitation to convene with the Exec Comm, sent very soon, will encourage them to hold their fire – at least for a while?

FC

From: Wholley, David (FNIH) [T] [b6]
Sent: Friday, May 8, 2020 7:03 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Melencio, Cheryl (FNIH) [T] [b6]; Wood, Gretchen (NIH/OD) [E] [b6]
Subject: RE: do we need an Executive Committee meeting with the co-chairs sooner rather than later?

Dear ACTIV Executive Committee Members and Working Group Co-Chairs:

Although our first formal ACTIV EC meeting is not scheduled until May 20, I am aware of some concerns that are being voiced among our Working Group members. Those focus on the next steps for ACTIV, and especially about implementation of the plans these groups have been working so hard to put together. There are also concerns about how we should best communicate across our partnership and coordinate with the many parallel (and in some cases conflicting) efforts that have emerged elsewhere—including among our own ACTIV members.

These are all very valid issues, and I believe they should be discussed by our dedicated team sooner rather than later. A meeting of the minds is particularly timely now, in the wake of a successful Leadership Team call on Wednesday and the establishment just this week of an Executive Committee to guide us moving forward. Therefore, I would like to make it a priority that the EC and the Working Group co-Chairs meet early next week to discuss and sync up on these important issues. Gretchen Wood on my staff will work with Cheryl Melencio at FNIH to reach out to you to get a suitable hourlong set up—a morning meeting would make it easier to include Tony Fauci (because of White House duties in the afternoon) and Paul Stoffels (because of European time zones).

Thanks for all you are doing for the cause, and best regards,

Francis

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Friday, May 8, 2020 6:27 PM
To: Wholley, David (FNIH) [T] [b6]
Cc: Melencio, Cheryl (FNIH) [T] [b6]; Wood, Gretchen (NIH/OD) [E] [b6]
Subject: Re: do we need an Executive Committee meeting with the co-chairs sooner rather than later?

That would be great, you read my mind.

Sent from my iPhone

On May 8, 2020, at 5:55 PM, Wholley, David (FNIH) [T] [b6] wrote:

Yes, by all means. I guess I should write a brief invitation note to come from you?

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Friday, May 8, 2020 5:04 PM
To: Wholley, David (FNIH) [T] [b6]
Subject: RE: do we need an Executive Committee meeting with the co-chairs sooner rather than later?

Totally agree. Could we aim for a meeting early next week? If it could be in the morning, we'd have a better chance to include Tony and Paul. I would make this a very high priority. Can Cheryl work on this with Gretchen?

FC

From: Wholley, David (FNIH) [T] [b6]
Sent: Friday, May 8, 2020 4:26 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: do we need an Executive Committee meeting with the co-chairs sooner rather than later?

Francis,
In talking with my team today, the same issues that the TX-Clinical group is writing about came up on the Clinical Trial Capacity call: we need better coordination of ACTIV with other external efforts that appear duplicative, we need better communications across groups, and above all it is time for us to make decisions about ACTIV implementation and to do that we need to understand how that will be funded and managed and where this is all going. This is coming from co-chairs and rank and file members of these Working Groups, from NIH and FDA and industry members, some of whom are fairly highly placed.

It seems to me we need a forum for a frank dialogue between the EC and the co-chairs to discuss and communicate on these issues. The Leadership Team calls are not the forum for this, and it should not be coming from me. I am worried that this chorus is going to continue to get louder if we don't speak sooner than our next scheduled EC, which would be May 20. I recommend we seek to set something up before then, focused on exactly these issues rather than the usual show and tell.

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
[b6]

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11400 Rockville Pike Suite 600 North Bethesda, MD 20852

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/9/2020 2:24:21 AM
To: Eric Hughes [b6] Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [b6]; Keith Gottesdiener [b6]; Elliott Levy [b6]; Wung, Peter /US [Peter.Wung@sanofi.com]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [b6]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: Follow-up from ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #8
Attachments: 2020-05-07_TX-Clinical_WG_Agent_Prioritization_Committee_Meeting Summary.pdf

Dear TX-Clinical Agent Prioritization Subgroup,

Thank you all for a very productive discussion on the re-evaluation of the criteria and how we will approach our next cycle of prioritization. Elizabeth and I are working on some materials for your review at our meetings next week.

For now, please find the formal summary of the meeting attached for your review. Please let me know if you have additions or amendments.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health
Direct: [b6] Mobile: [b6]
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APAR0000005457

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CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [b6]; Jansen, Kathrin [b6]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [b6]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan [jwachtel@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Alvarez, Rosa [rosalvarez@deloitte.com]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Anderson, Margaret [marganderson@deloitte.com]; Lucas

SmallDon: [b6] Stratton, Benjamin [bstratton@DELOITTE.com]; Qashu, Felicia
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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Subject: Follow-up from the ACTIV TX-Clinical Working Group #5

Attachments: 2020-05-07_TX-Clinical_WG_Meeting_Summary.pdf

Dear TX-Clinical Working Group,

Please find attached the formal summary from yesterday's WG meeting. I want to thank you all for your candid feedback and earnest desire to see this process succeed. All your time and efforts are truly greatly appreciated!

Some of you have reached out to ask, so I will note, that no, you have not missed the letter that the team is drafting to the ACTIV Executive Committee. The group is just working to ensure the best possible case is made for the group's request. We hope to share the note with you all soon for review.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
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CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [b6]; Jansen, Kathrin [b6]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [b6]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [marganderson@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Carluccio, Dana [b6]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny [b6]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [b6]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveson, Nancy [b6]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Criffield, Robin [b6]; Hamilton, Nancy [b6]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Minnich, Beth [b6]; Mueller-Reichenstein, Petra [b6]; Quadros, Nora [b6]; Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Hill, Zoe (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]
Subject: Summary and action items - CT Capacity WG meeting #7

Attachments: Clinical_Trial_Capacity_Working_Group_Meeting 7_Summary_Final.pdf

Dear Clinical Trial Capacity Working Group Members,

Attached is the summary and action items for meeting #7 (May 8, 2020) of the full working group. The next full working group meeting is scheduled for Friday, May 8 at 9 am eastern time USA.

Best regards,

Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health

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CC: Mary Biggs [b6]; Demarcus [b6]; Macone, Erin [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [b6]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Eron, Joseph J Jr [b6]
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End: 5/11/2020 6:30:00 PM
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Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butters; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Patterson, Amy (NIH/NHLBI) [E]; Smith, David; Kim, Peter (NIH/NIAID) [E]; **b6**; Eron, Joe; Higgs, Elizabeth (NIH/NIAID) [E]

Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Eron, Joseph J Jr

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Subject: slides from today and ACTIV Vaccine Committee
Attachments: harmonized versus compartaive trials_.pptx

Flag: Follow up

Francis , here are this morning's slides . As John articulated on the phone he and I have had frequent communication with Doug ; debriefing each week for an hour just the three of us . Last Thursday, we have outlined the strategy for the recently composed Clinical Development subcommittee of the Vaccine Committee . I lead this subcommittee with Paula Annunziato from Merck . Paula and I had an hour talk Saturday night (yes a zoom date) to go through the agenda for this Wednesday's upcoming call . We will be sending everyone the Science article we wrote coming out Monday as background. We will then outline the goals of the clinical development and then move to discussing key harmonized elements ; let them all interact . on key issues mainly the endpoints , populations , and we will raise the issue of the common DSMB and their ability to send suggestions to Doug and you .. We expanded the subcommittee so that all the Pharma companies on the BARDA list are represented so they will be a part of the process . Paula is a big fan of the harmonized design ; she voices the issue all Pharma companies have in a real viable market ; they don't want head to head comparisons ; parallel universes is how they always operate .
The global strategy and the link to WHO are my next on the plate issues perhaps worth a chat.
If there are other issues of concern just call My cell is [b6].
Thanks Larry

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/11/2020 2:20:00 AM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [b6]; Eisner, Mark [b6]; Gottesdiener, Keith [b6]; Hughes, Eric [b6]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; LaVange, Lisa [b6]; Levy, Elliot [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [b6]; Patel, Naimish [b6]; Peppercorn, Amanda; Poole, Mike [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Amanda Peppercorn [b6]; Garner, Carl [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Burgess, Timothy [b6]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]
CC: Kim, Elizabeth [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]
Subject: Updates from Last Wednesday's ACTIV Leadership Meeting
Attachments: ACTIV Partnership Leadership Team Meeting 20200506 FINAL2.pdf; 2020-05-06_ACTIV_Leadership_Group_Meeting_Summary FINAL.pdf

Dear ACTIV Therapeutics-Clinical Working Group,

I wanted to share with you some summary materials for the current standing of all 4 working groups within ACTIV. In the hope of providing more clarity into the overarching connectivity of the working group and the directions of the partnership.

Last Wednesday, the ACTIV Leadership Team (the parent body above the Working Groups) met. Sarah and Eric presented the progress and plans of our Working Group and answered questions. The meeting presentation and notes are attached which include similar summaries from all the Working Groups.

If you have specific questions, let us know and we can follow up.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Foundation for the National Institutes of Health

Direct: b6 Mobile: b6

fnih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Tabak, Lawrence (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02E22836B5FF4E9988E3770CFC7EE770-TABAKL]
Sent: 5/11/2020 2:35:43 AM
To: Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]
CC: Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]
Subject: FW: slides from today and ACTIV Vaccine Committee

Need to participate in this tomorrow 11:15-11:45, so Julie will need to be rescheduled.

Sorry

Larry

From: Francis Collins [b6]
Date: Sunday, May 10, 2020 at 10:32 PM
To: "Tabak, Lawrence (NIH/OD) [E]" [b6] "Santos, Michael (FNIH) [T]" [b6] "Wholley, David (FNIH) [T]" [b6] "Lane, Cliff (NIH/NIAID) [E]" [b6]
Subject: RE: slides from today and ACTIV Vaccine Committee

That would be great.

From: Tabak, Lawrence (NIH/OD) [E] [b6]
Sent: Sunday, May 10, 2020 10:32 PM
To: Collins, Francis (NIH/OD) [E] [b6] Santos, Michael (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6] Lane, Cliff (NIH/NIAID) [E] [b6]
Subject: Re: slides from today and ACTIV Vaccine Committee

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To: "Santos, Michael (FNIH) [T]" [b6] "Tabak, Lawrence (NIH/OD) [E]" [b6] "Wholley, David (FNIH) [T]" [b6] "Lane, Cliff (NIH/NIAID) [E]" [b6]
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I can probably make that work. Please send information about how to link in.

From: Santos, Michael (FNIH) [T] [b6]
Sent: Sunday, May 10, 2020 10:09 PM
To: Collins, Francis (NIH/OD) [E] [b6] Tabak, Lawrence (NIH/OD) [E] [b6] Wholley, David (FNIH) [T] [b6] Lane, Cliff (NIH/NIAID) [E] [b6]
Subject: RE: slides from today and ACTIV Vaccine Committee

Hi Francis,

I have a regularly scheduled call with Kathrin and Doug at 11:15-11:45am tomorrow (Monday) morning. If you can be free then and would like to join, that's an option. If that doesn't work, we can find another time before the Wednesday meeting (1pm).

Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Tabak, Lawrence (NIH/OD) [E] [b6]
Sent: Sunday, May 10, 2020 10:00 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]
Subject: Re: slides from today and ACTIV Vaccine Committee

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Despite the reassurance on the call today that the issues have been socialized with the WG, I recommend that we do have a separate discussion with them. We should do everything possible to make this transition as smoothly as possible.
Larry

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Date: Sunday, May 10, 2020 at 9:52 PM
To: "Wholley, David (FNIH) [T]" [b6]; "Santos, Michael (FNIH) [T]" [b6];
"Tabak, Lawrence (NIH/OD) [E]" [b6]; "Lane, Cliff (NIH/NIAID) [E]" [b6]
Subject: FW: slides from today and ACTIV Vaccine Committee

See slides and note from Larry Corey.

Do we need a separate discussion with the Vaccines WG before their Wednesday meeting?

FC

From: Corey MD, Larry [b6]
Sent: Sunday, May 10, 2020 9:35 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: slides from today and ACTIV Vaccine Committee

Francis , here are this morning's slides . As John articulated on the phone he and I have had frequent communication with Doug ; debriefing each week for an hour just the three of us . Last Thursday, we have outlined the strategy for the recently composed Clinical Development subcommittee of the Vaccine Committee . I lead this subcommittee with Paula Annunziato from Merck . Paula and I had an hour talk Saturday night (yes a zoom date) to go through the agenda for this Wednesday's upcoming call . We will be sending everyone the Science article we wrote coming out Monday as background. We will then outline the goals of the clinical development and then move to discussing key harmonized elements ; let them all interact . on key issues mainly the endpoints , populations , and we will raise the issue of the common DSMB and their ability to send suggestions to Doug and you .. We expanded the subcommittee so that all the Pharma companies on the BARDA list are represented so they will be a part of the process . Paula is a big fan of

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The global strategy and the link to WHO are my next on the plate issues perhaps worth a chat.

If there are other issues of concern just call My cell is b6 .

Thanks Larry

From: Tabak, Lawrence (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02E22836B5FF4E9988E3770CFC7EE770-TABAKL]
Sent: 5/11/2020 2:38:04 AM
To: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]
Subject: Re: slides from today and ACTIV Vaccine Committee

thanks

From: "Santos, Michael (FNIH) [T]" [b6]
Date: Sunday, May 10, 2020 at 10:35 PM
To: "Tabak, Lawrence (NIH/OD) [E]" [b6], Francis Collins [b6]
"Wholley, David (FNIH) [T]" [b6], "Lane, Cliff (NIH/NIAID) [E]" [b6]
Subject: RE: slides from today and ACTIV Vaccine Committee

Thanks, Francis and Larry. I have added you to the invite, which you should have just received.

I will let Kathrin and Doug know that you'll be joining to discuss this topic.

Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Tabak, Lawrence (NIH/OD) [E] [b6]
Sent: Sunday, May 10, 2020 10:35 PM
To: Collins, Francis (NIH/OD) [E] [b6], Santos, Michael (FNIH) [T] [b6], Wholley, David (FNIH) [T] [b6], Lane, Cliff (NIH/NIAID) [E] [b6]
Subject: Re: slides from today and ACTIV Vaccine Committee

Ok – Mike, please send me log-in information as well.
Thanks
Larry

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To: "Tabak, Lawrence (NIH/OD) [E]" [b6], "Santos, Michael (FNIH) [T]" [b6]
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Wholley, David (FNIH) [T] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]
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Sent: Sunday, May 10, 2020 10:00 PM
To: Collins, Francis (NIH/OD) [E] [b6], Wholley, David (FNIH) [T] [b6], Santos, Michael (FNIH) [T] [b6], Lane, Cliff (NIH/NIAID) [E] [b6]
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"Tabak, Lawrence (NIH/OD) [E]" [b6], "Lane, Cliff (NIH/NIAID) [E]" [b6]
Subject: FW: slides from today and ACTIV Vaccine Committee

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 5/11/2020 11:42:13 AM
To: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]
Subject: RE: slides from today and ACTIV Vaccine Committee
Flag: Follow up

I absolutely think we need to talk to the WG and share the nuances of the conversation.

From: Santos, Michael (FNIH) [T] [b6]
Sent: Sunday, May 10, 2020 10:09 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Wholley, David (FNIH) [T] [b6]; Lane, Cliff (NIH/NIAID) [E] <clane@niaid.nih.gov>
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b6

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b6

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Sent: 5/11/2020 1:58:43 PM
To: Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]
Subject: FW: Time sensitive -- ACTIV mtg with Exec Comm and WG co-chairs

From: "Wood, Gretchen (NIH/OD) [E]" [b6]
Date: Monday, May 11, 2020 at 9:23 AM
To: Francis Collins [b6], Anthony Fauci [b6], "Gibbons, Gary (NIH/NHLBI) [E]" [b6], "Stoffels, Paul" [b6], "Pao, William" [b6], "Dolsten, Mikael" [b6], "Colvis, Christine (NIH/NCATS) [E]" [b6], "Desrosiers, Betsy" [b6], "Hughes, Eric" [b6], "Jansen, Kathrin" [b6], "Kurilla, Michael (NIH/NCATS) [E]" [b6], "Lowy, Douglas (NCI)" [b6], "Read, Sarah (NIH/NIAID) [E]" [b6], "Young, John" [b6]
Cc: "Wholley, David (FNIH) [T]" [b6], "Menetski, Joseph (FNIH) [T]" [b6], "Adam, Stacey (FNIH) [T]" [b6], "Tountas, Karen (FNIH) [T]" [b6], "Santos, Michael (FNIH) [T]" [b6], "Freire, Maria (FNIH) [T]" [b6], "Tabak, Lawrence (NIH/OD) [E]" [b6], "Lane, Cliff (NIH/NIAID) [E]" [b6], "Parker, Ashley (NIH/OD) [E]" [b6], "Anderson, James (NIH/OD) [E]" [b6], "Austin, Christopher (NIH/NCATS) [E]" [b6], "Melencio, Cheryl (FNIH) [T]" [b6]
Subject: Re: Time sensitive -- ACTIV mtg with Exec Comm and WG co-chairs

Good morning,

Please mark your calendars for Wednesday, May 13, from 8:00 AM-9:00 AM ET for this call. A calendar invitation will be shared with you soon.

With very best wishes,

Gretchen

From: Francis Collins [b6]
Date: Saturday, May 9, 2020 at 1:07 PM
To: Francis Collins [b6], Anthony Fauci [b6], "Gibbons, Gary (NIH/NHLBI) [E]" [b6], [b6] [b6], Gretchen Wood [b6], "Pao, William" [b6], "Colvis, Christine (NIH/NCATS) [E]" [b6], "Desrosiers, Betsy" [b6], "Hughes, Eric" [b6], "Jansen, Kathrin" [b6], "Kurilla, Michael (NIH/NCATS) [E]" [b6], "Lowy, Douglas (NCI)" [b6], "Read, Sarah (NIH/NIAID) [E]" [b6], "Young, John" [b6]
Cc: David Wholley [b6], "Menetski, Joseph (FNIH) [T]" [b6], "Adam, Stacey

(FNIH) [T]" [b6] , "Tountas, Karen (FNIH) [T]" [b6] , "Santos, Michael (FNIH) [T]"
[b6] Maria Freire [b6] "Tabak, Lawrence (NIH/OD) [E]"
[b6] , "Lane, Cliff (NIH/NIAID) [E]" [b6] Ashley Parker
James Anderson [b6] "Austin, Christopher (NIH/NCATS)
[b6] "Melencio, Cheryl (FNIH) [T]" [b6] Gretchen Wood

Subject: Time sensitive -- ACTIV mtg with Exec Comm and WG co-chairs

Dear ACTIV Executive Committee Members and Working Group Co-Chairs:

Although our next formal ACTIV EC meeting is not scheduled until May 20, I am aware of some concerns that are being voiced among our Working Group members. Some of those focus on the next steps for ACTIV, and especially about implementation of the plans these groups have been working so hard to put together. [b5]

b5

These are all very valid issues, and I believe they should be discussed by our dedicated team sooner rather than later. A meeting of the minds is particularly timely now, in the wake of a successful Leadership Team call on Wednesday and the establishment just this week of an Executive Committee to guide us moving forward. Therefore, I would like to make it a priority that the EC and the Working Group co-Chairs meet early next week to discuss and sync up on these important issues. Gretchen Wood on my staff will work with Cheryl Melencio at FNIH to reach out to you to get a suitable hourlong virtual conference set up—a morning meeting would make it easier to include Tony Fauci (because of White House duties in the afternoon) and Paul Stoffels (because of European time zones).

Thanks for all you are doing for the cause, and best regards,

Francis

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 5/11/2020 2:08:33 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Dolsten, Mikael [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Pao, William [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabca2247548e596778304f781f-austinc];
CC: Barasch, Kimberly (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Conrad, Patricia (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Protasiewicz, Ann [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Zanelato, Ann [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Zottoli, Jessica [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Togashi, Mieko (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs];

(FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togashim]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]

Subject: ACTIV mtg with Exec Comm and WG co-chairs

Location: b6

Start: 5/13/2020 12:00:00 PM

End: 5/13/2020 1:00:00 PM

Show Time As: Tentative

Required Attendees: Collins, Francis (NIH/OD) [E]; Dolsten, Mikael; Fauci, Anthony (NIH/NIAID) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Pao, William; Stoffels, Paul; Woodcock, Janet (FDA/CDER); Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Wholley, David; Menetski, Joseph; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Freire, Maria (FNIH) [T]; Tabak, Lawrence (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]

Optional Attendees: Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Protasiewicz, Ann; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Zanelato, Ann; Zottoli, Jessica; Togashi, Mieko (NIH/NCI) [E]; Sepulveda, Dorina (FNIH) [T]; Lagos, Enrique (NIH/NCATS) [E]; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 5/11/2020 2:08:35 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Dolsten, Mikael [b6] Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Pao, William [b6] Stoffels, Paul [b6] Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [b6] Hughes, Eric [b6] Jansen, Kathrin [b6] Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [b6] Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]
CC: Barasch, Kimberly (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Conrad, Patricia (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Protasiewicz, Ann [b6] Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Zanelato, Ann

[b6] Zottoli, Jessica [b6] Togashi, Mieko (NIH/NCI) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togashim]; Sepulveda, Dorina (FNIH)
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Lagos, Enrique
(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Simon, Dina (NIH/OD) [C]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]

Subject: ACTIV mtg with Exec Comm and WG co-chairs

Location: [b6]

Start: 5/13/2020 12:00:00 PM

End: 5/13/2020 1:00:00 PM

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Required Attendees: Collins, Francis (NIH/OD) [E]; Dolsten, Mikael; Fauci, Anthony (NIH/NIAID) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Pao, William; Stoffels, Paul; Woodcock, Janet (FDA/CDER); Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Wholley, David; Menetski, Joseph; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Freire, Maria (FNIH) [T]; Tabak, Lawrence (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]
Optional Attendees: Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Protasiewicz, Ann; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Zanelato, Ann; Zottoli, Jessica; Togashi, Mieko (NIH/NCI) [E]; Sepulveda, Dorina (FNIH) [T]; Lagos, Enrique (NIH/NCATS) [E]; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 5/11/2020 2:08:35 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Dolsten, Mikael [b6]; Fauci, Anthony (NIH/NIAID) [E] [b6]; Gibbons, Gary (NIH/NHLBI) [E] [b6]; Pao, William [b6]; Stoffels, Paul [b6]; Woodcock, Janet (FDA/CDER) [b6]; Colvis, Christine (NIH/NCATS) [E] [b6]; Desrosiers, Betsy [b6]; Hughes, Eric [b6]; Jansen, Kathrin [b6]; Kurilla, Michael (NIH/NCATS) [E] [b6]; Lowy, Douglas (NCI) [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Young, John [b6]; Wholley, David (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Barasch, Kimberly (NIH/NIAID) [C] [b6]; Conrad, Patricia (NIH/NIAID) [E] [b6]; Dimishkov, Roxanne (NIH/NHLBI) [C] [b6]; McManus, Ayanna (NIH/OD) [E] [b6]; Protasiewicz, Ann [b6]; Thomas, Ashley (FDA/CDER) [b6]; Wood, Gretchen (NIH/OD) [E] [b6]; Zanellato, Ann [b6]; Zottoli, Jessica [b6]; Togashi, Mieko (NIH/NCI) [E] [b6]; Sepulveda, Dorina (FNIH) [T] [b6]; Lagos, Enrique (NIH/NCATS) [E] [b6]; Simon, Dina (NIH/OD) [C] [b6]; Burrus-Shaw, Cyndi (NIH/OD) [E] [b6]; Hardesty, Rebecca (NIH/OD) [C] [b6]; Alvarez, Rosa [rosalvarez@deloitte.com]; Anderson, Margaret [marganderson@deloitte.com]; Elsaid, Olivia [oelsaid@deloitte.com]; Gonzalez, Nina [ningonzalez@deloitte.com]; Kim, Elizabeth [elkim@deloitte.com]; Stratton, Ben [bstratton@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Wachtel, Jonathan [jwachtel@deloitte.com]

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Subject: ACTIV mtg with Exec Comm and WG co-chairs

Location: [b6]

Start: 5/13/2020 12:00:00 PM

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Required Attendees: Collins, Francis (NIH/OD) [E]; Dolsten, Mikael; Fauci, Anthony (NIH/NIAID) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Pao, William; Stoffels, Paul; Woodcock, Janet (FDA/CDER); Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Wholley, David (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Freire, Maria (FNIH) [T]; Tabak, Lawrence (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]; Wolinetz, Carrie (NIH/OD) [E]

Optional Attendees: Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Protasiewicz, Ann; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Zanellato, Ann; Zottoli, Jessica; Togashi, Mieko (NIH/NCI) [E]; Sepulveda, Dorina (FNIH) [T]; Lagos, Enrique (NIH/NCATS) [E]; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Hardesty, Rebecca (NIH/OD) [C]; Alvarez, Rosa; Anderson, Margaret; Elsaid, Olivia; Gonzalez, Nina; Kim, Elizabeth; Stratton, Ben; Tolman, Brett; Wachtel, Jonathan

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CC: Barasch, Kimberly (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Conrad, Patricia (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Protasiewicz, Ann [b6]; Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen

(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Zanelato, Ann
[b6]; Zottoli, Jessica [b6]; Togashi, Mieko (NIH/NCI) [E]
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togashim]; Sepulveda, Dorina (FNIH)
[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[/o=ExchangeLabs/ou=Exchange Administrative Group
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(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Hardesty, Rebecca (NIH/OD)
[C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=21465ceb763947408d209aaabf10af70-hardestyrs]; Alvarez, Rosa
[rosalvarez@deloitte.com]; Anderson, Margaret [marganderson@deloitte.com]; Elsaid, Olivia
[oelsaid@deloitte.com]; Gonzalez, Nina [ningonzalez@deloitte.com]; Kim, Elizabeth [elkim@deloitte.com]; Stratton,
Ben [bstratton@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Wachtel, Jonathan [jwachtel@deloitte.com]

Subject: ACTIV mtg with Exec Comm and WG co-chairs

Attachments: Agenda for ACTIV EC meeting tomorrow morning at 8:00 AM Eastern US Time; Notes _Agenda ACTIV EC Meeting #1
5-13-20.docx

Location: [b6]

Start: 5/13/2020 12:00:00 PM

End: 5/13/2020 1:00:00 PM

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Required Attendees: Collins, Francis (NIH/OD) [E]; Dolsten, Mikael; Fauci, Anthony (NIH/NIAID) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Pao, William; Stoffels, Paul; Woodcock, Janet (FDA/CDER); Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Wholley, David (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Freire, Maria (FNIH) [T]; Tabak, Lawrence (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]; Wolinetz, Carrie (NIH/OD) [E]
Optional Attendees: Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Protasiewicz, Ann; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Zanelato, Ann; Zottoli, Jessica; Togashi, Mieko (NIH/NCI) [E]; Sepulveda, Dorina (FNIH) [T]; Lagos, Enrique (NIH/NCATS) [E]; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Hardesty, Rebecca (NIH/OD) [C]; Alvarez, Rosa; Anderson, Margaret; Elsaid, Olivia; Gonzalez, Nina; Kim, Elizabeth; Stratton, Ben; Tolman, Brett; Wachtel, Jonathan

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CC: Mary Biggs [b6]; Demarcus [b6]; Macone, Erin [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [b6]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Eron, Joseph J Jr [b6]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]
Subject: Materials for ACTIV TX-Clinical Master Protocol Subgroup #15
Attachments: ACTIV Therapeutics-Clinical_MP Subgroup_11May2020 Meeting Guide.pdf; Adapt Out COVID Overview051120.pdf

Dear TX-Clinical Master Protocol Subgroup,

Please find attached the materials for today’s call. We will be discussing the statistical simulations the group has put together for ACTT-3, as well as we will have a presentation from the ACTG group on their outpatient master protocol.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

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CC: Mary Biggs [b6]; Demarcus [b6]; Macone, Erin [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [b6]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Eron, Joseph J Jr [b6]; Javan, Arzhang (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]
Subject: ACTIV TX-Clinical Master Protocol Subgroup #15
Attachments: ACTIV Therapeutics-Clinical_MP Subgroup_11May2020 Meeting Guide.pdf; Adapt Out COVID Overview051120.pdf
Location: [b6]

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Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Patterson, Amy (NIH/NHLBI) [E]; Smith, David; Kim, Peter (NIH/NIAID) [E]; [b6] Eron, Joe; Higgs, Elizabeth (NIH/NIAID) [E]; Burgess, Timothy; Beumont-Mauviel, Maria [JRDUS]; Peeters, Monika [JRDBE]; Woodfall, Brian [JRDUS]; Van Heeswijk, Rolf [JRDBE]

Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Eron, Joseph J Jr; Javan, Arzhang (NIH/NIAID) [E]

Dear TX-Clinical Master Protocol Subgroup,

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Thanks,
Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/11/2020 4:02:44 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [b6] Eisner, Mark [b6] Gottesdiener, Keith [b6] Hughes, Eric [b6] Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; LaVange, Lisa [b6] Levy, Elliot [b6] Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [b6] Patel, Naimish [naimish.patel@sanofi.com]; Peppercorn, Amanda [b6] Poole, Mike [b6] Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Amanda Peppercorn [b6] Garner, Carl [b6] Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Burgess, Timothy [b6]
CC: Kim, Elizabeth [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: Letter to the ACTIV Executive Committee for Group's Review
Attachments: Proposal for ACTIV leadership-v8.docx

Dear TX-Clinical Working Group members,

As discussed on last Thursday's call, the small writing team (Carl, Keith, Amanda, Judy, Libby, and Peter) have worked with the co-chairs to formulate the attached letter that attempted to capture the challenges and concerns that were expressed by the group.

They would now like to have the group review and comment if desired before the note is sent to the ACTIV Executive Committee tomorrow ahead of their scheduled meeting on Wednesday this week. **Therefore, we would ask the group to review and send any comments they have or any edits they think absolutely critical by 9AM tomorrow (May 12).** Any necessary updates will be made and then the letter will be sent on to the Executive Committee.

The team would also like to send this on behalf of the whole group with all the group members listed. **Please let us know if you are okay with this plan.**

Thank you all for your efforts and strong desire to see our remit for this partnership succeed!

Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Foundation for the National Institutes of Health

Direct: **b6** Mobile: **b6**

fniih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fniih.org/pandemic



From: Hardesty, Rebecca (NIH/OD) [C] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=21465CEB763947408D209AAABF10AF70-HARDESTYRS]
Sent: 5/11/2020 4:47:36 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]
Subject: RE: Time sensitive -- ACTIV mtg with Exec Comm and WG co-chairs

Thank you very much, Cheryl and Ashley!

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Monday, May 11, 2020 12:47 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Wood, Gretchen (NIH/OD) [E] [b6]
Cc: Hardesty, Rebecca (NIH/OD) [C] [b6]
Subject: RE: Time sensitive -- ACTIV mtg with Exec Comm and WG co-chairs

I'll send her the invite and copy her assistant, Rebecca.

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

[b6]
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11400 Rockville Pike Suite 600 North Bethesda, MD 20852

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From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, May 11, 2020 12:46 PM
To: Wood, Gretchen (NIH/OD) [E] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
Cc: Hardesty, Rebecca (NIH/OD) [C] [b6]
Subject: RE: Time sensitive -- ACTIV mtg with Exec Comm and WG co-chairs

Hi Gretchen and Cheryl,

Dr. Carrie Wolinetz would like to join this meeting. Cheryl – should I forward the invite or would you prefer to add on your end?

Thank you,
Ashley

APAR0000006700

From: Wood, Gretchen (NIH/OD) [E] [b6] >
Sent: Monday, May 11, 2020 9:23 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Fauci, Anthony (NIH/NIAID) [E] [b6]; Gibbons, Gary (NIH/NHLBI) [E] [b6]; Stoffels, Paul [b6]; Pao, William [b6]; Dolsten, Mikael [b6]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy [b6]; Hughes, Eric [b6]; Jansen, Kathrin [b6]; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI) [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Young, John [b6]
Cc: Wholley, David (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
Subject: Re: Time sensitive -- ACTIV mtg with Exec Comm and WG co-chairs

Good morning,

Please mark your calendars for Wednesday, May 13, from 8:00 AM-9:00 AM ET for this call. A calendar invitation will be shared with you soon.

With very best wishes,

Gretchen

From: Francis Collins [b6]
Date: Saturday, May 9, 2020 at 1:07 PM
To: Francis Collins [b6]; Anthony Fauci [b6]; Gibbons, Gary (NIH/NHLBI) [E] [b6]; Gretchen Wood [b6]; "Pao, William" [b6]; "Colvis, Christine (NIH/NCATS) [E]" [b6]; "Desrosiers, Betsy" [b6]; "Hughes, Eric" [b6]; "Jansen, Kathrin" [b6]; "Kurilla, Michael (NIH/NCATS) [E]" [b6]; "Lowy, Douglas (NCI)" [b6]; "Read, Sarah (NIH/NIAID) [E]" [b6]; "Young, John" [b6]
Cc: David Wholley [b6]; "Menetski, Joseph (FNIH) [T]" [b6]; "Adam, Stacey (FNIH) [T]" [b6]; "Tountas, Karen (FNIH) [T]" [b6]; "Santos, Michael (FNIH) [T]" [b6]; Maria Freire [b6]; "Tabak, Lawrence (NIH/OD) [E]" [b6]; "Lane, Cliff (NIH/NIAID) [E]" [b6]; Ashley Parker [b6]; James Anderson [b6]; "Austin, Christopher (NIH/NCATS) [E]" [b6]; "Melencio, Cheryl (FNIH) [T]" [b6]; Gretchen Wood [b6]
Subject: Time sensitive -- ACTIV mtg with Exec Comm and WG co-chairs

Dear ACTIV Executive Committee Members and Working Group Co-Chairs:

Although our next formal ACTIV EC meeting is not scheduled until May 20, I am aware of some concerns that are being voiced among our Working Group members. Some of those focus on the next steps for ACTIV, and especially about implementation of the plans these groups have been working so hard to put together. [b5]

b5

These are all very valid issues, and I believe they should be discussed by our dedicated team sooner rather than later. A meeting of the minds is particularly timely now, in the wake of a successful Leadership Team call on Wednesday and the establishment just this week of an Executive Committee to guide us moving forward. Therefore, I would like to make it a priority that the EC and the Working Group co-Chairs meet early next week to discuss and sync up on these important issues. Gretchen Wood on my staff will work with Cheryl Melencio at FNIH to reach out to you to get a suitable hourlong virtual conference set up—a morning meeting would make it easier to include Tony Fauci (because of White House duties in the afternoon) and Paul Stoffels (because of European time zones).

Thanks for all you are doing for the cause, and best regards,

Francis

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/11/2020 4:47:38 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]
CC: Hardesty, Rebecca (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21465ceb763947408d209aaabf10af70-hardestyrs]
Subject: RE: Time sensitive -- ACTIV mtg with Exec Comm and WG co-chairs

Thanks so much, Cheryl!

From: Melencio, Cheryl (FNIH) [T] { b6
Sent: Monday, May 11, 2020 12:47 PM
To: Parker, Ashley (NIH/OD) [E] { b6 }; Wood, Gretchen (NIH/OD) [E] { b6
Cc: Hardesty, Rebecca (NIH/OD) [C] { b6
Subject: RE: Time sensitive -- ACTIV mtg with Exec Comm and WG co-chairs

I'll send her the invite and copy her assistant, Rebecca.

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

{ b6
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

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From: Parker, Ashley (NIH/OD) [E] { b6
Sent: Monday, May 11, 2020 12:46 PM
To: Wood, Gretchen (NIH/OD) [E] { b6 }; Melencio, Cheryl (FNIH) [T] { b6
Cc: Hardesty, Rebecca (NIH/OD) [C] { b6
Subject: RE: Time sensitive -- ACTIV mtg with Exec Comm and WG co-chairs

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From: Wood, Gretchen (NIH/OD) [E] [b6]
Sent: Monday, May 11, 2020 9:23 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Fauci, Anthony (NIH/NIAID) [E] [b6]; Gibbons, Gary (NIH/NHLBI) [E] [b6]; Stoffels, Paul [b6]; Pao, William [b6]; Dolsten, Mikael [b6]; Colvis, Christine (NIH/NCATS) [E] [b6]; Desrosiers, Betsy [b6]; Hughes, Eric [b6]; Jansen, Kathrin [b6]; Kurilla, Michael (NIH/NCATS) [E] [b6]; Lowy, Douglas (NCI) [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Young, John [b6]
Cc: Wholley, David (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
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From: Francis Collins [b6]
Date: Saturday, May 9, 2020 at 1:07 PM
To: Francis Collins [b6]; Anthony Fauci [b6]; Gibbons, Gary (NIH/NHLBI) [E] [b6]; Gretchen Wood [b6]; Pao, William [b6]; Colvis, Christine (NIH/NCATS) [E] [b6]; Desrosiers, Betsy [b6]; Hughes, Eric [b6]; Jansen, Kathrin [b6]; Kurilla, Michael (NIH/NCATS) [E] [b6]; Lowy, Douglas (NCI) [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Young, John [b6]
Cc: David Wholley [b6]; Menetski, Joseph (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]; Maria Freire [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Ashley Parker [b6]; James Anderson [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Gretchen Wood [b6]
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Francis

From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
Sent: 5/11/2020 8:49:55 PM
To: Bascles, Lionel [b6]; Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [b6]; Desrosiers, Betsy [b6]; Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshow, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshoj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; King, James (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce1f3853e43d4463a04f7d74992f96ac-James.King.]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura [b6]; Srinivasan, Badhri [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Vincent, Mike [b6]; Wachtel, Jonathan [jwachtel@deloitte.com]; Garner, Carlos [b6]; Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]
CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [b6]; Jansen, Kathrin [b6]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [b6]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [marganderson@deloitte.com]; Carluccio, Dana [b6]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny [b6]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [b6]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveson, Nancy [b6]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Criffield, Robin [b6]; Hamilton, Nancy [b6]; Minnich, Beth [b6]; Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Stratton, Benjamin [bstratton@DELOITTE.com]; Tolman, Brett [btolman@deloitte.com]; Kenny, Dermot [b6]

b6
b6; Haynes, Barton [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d4a05845b5b4069ad0447fb60ebfa79-hayne002.mc];
b6; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5];
b6; Offit, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cdb9cc56fde4598a57b423d484dcf9f-offit.email]; b6
Seals, Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a87d49ccb4e3caaf5eb5d3586b1cc-Jonathan.Se];
b6 Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbf6108d53148f684dad333fce983de-aarvin.stan];
b6
b6 Johnson, Maureen (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr]; Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Jintanat Ananworanich
b6; Michael Watson (x) b6; Verani, Jennifer R. (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c249692151d46d6ac80cb28ada3d3a0-qzr7]; Schrag, Stephanie (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9be29b344ba14363bdecaa43582ca226-ZHA6]; Marovich, Mary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bfd0192d165d4643accf6347728dbaeb-marovichma]

Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting
Attachments: Clinical Trial Capacity Working Group Meeting Agenda_05122020.pdf
Location: b6

Start: 5/12/2020 3:00:00 PM
End: 5/12/2020 4:00:00 PM
Show Time As: Tentative

Recurrence: Weekly
every Tuesday and Friday from 9:00 AM to 10:00 AM

Required Attendees: Bascles, Lionel; Cohen, Myron; Corey, Larry; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshov, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; King, James; Kurilla, Mike; Nayak, Seema (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Payton, Manzone; Resnansky, Laura; Srinivasan, Badhri; Stein, Peter (FDA/CBER); Vincent, Mike; Wachtel, Jonathan; Garner, Carlos; Sizemore, Christine (NIH/FIC) [E]; Qashu, Felicia
Optional Attendees: Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Carluccio, Dana; Cheryl (FNIH) Melencio [T]
b6; Francis Collins; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH); Tuveson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Minnich, Beth; Rebecca (NIH/NCATS) Katz [E] b6; Stratton, Benjamin; Tolman, Brett; Kenny,
b6
b6 Haynes, Barton; b6
b6 Lowy, Douglas (NIH/NCI) [E]; Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E];

Messonnier, Nancy (CDC/DDID/NCIRD/OD); [b6]; Offit, Paul; [b6]; Seals,
Jonathan (OS/ASPR/BARDA); [b6]; Arvin, Ann; [b6]
[b6]; Johnson, Maureen
(NIH/NCI) [E]; Kozlowski, Mary (NIH/NCI) [C]; Austin, Sarah (NIH/NIAID) [E]; Davey, Victoria; Jintanat Ananworanich;
Michael Watson (x); Verani, Jennifer R. (CDC/DDID/NCIRD/DBD); Schrag, Stephanie (CDC/DDID/NCIRD/DBD);
Marovich, Mary (NIH/NIAID) [E]

Dear Colleagues, Attached is the meeting agenda. Looking forward to a robust discussion about vaccine protocols and capacity needs! Karen

ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines

Dear Clinical Trial Capacity Working Group members,

In anticipation of this working group making rapid progress on identified action items and other activities, the co-chairs have agreed that it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify areas of need, and to determine next steps. We ask that you make every effort possible to join each of these meetings, but understand that at times you may have competing priorities. To place a hold on your calendar, please accept this meeting invite with a response; later you can decline an individual meeting if you have a conflict.

An agenda and other meeting materials, as needed, will be distributed prior to each call.

With best regards,
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health

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Password: [b6]

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/11/2020 10:50:52 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Coll]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [b6]; Keith Gottesdiener [b6]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Elliott Levy [b6]; Sandeep Menon [b6]; Amanda Peppercorn [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [b6]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [b6]; Wung, Peter /US [b6]; Karen Lynn Price [b6]; Pamela Tenaerts, M.D. [b6]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Smith, David [b6]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; [b6]; Eron, Joe [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Burgess, Timothy [b6]; Beumont-Mauviel, Maria [JRDUS] [b6]; Peeters, Monika [JRDBE] [b6]; Woodfall, Brian [JRDUS] [b6]; Van Heeswijk, Rolf [JRDBE] [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Ghosh, Pranab [b6]; Le Corre, Christophe [b6]
CC: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Eron, Joseph J Jr [b6]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]
Subject: Follow-up from ACTIV TX-Clinical Master Protocol Subgroup #15
Attachments: ACTIV_Therapeutics-Clinical_MP Sub-Group Meeting 11May2020_Key Takeaways.pdf; ACTIV Therapeutics-Clinical_MP Subgroup_11May2020 Meeting Guide.pdf; Adapt Out COVID Overview051120.pdf

Dear TX-Clinical Master Protocol Subgroup,

Thank you all for a great call today and giving us an extra 30 minutes more than usual to allow us to hear the presentation from the ACTG group on their outpatient master protocol.

We also want to say huge thank you to Sandeep, Pranab, and Christophe for the very good and very fast simulation work that they put together for ACTT-3. All the pieces for our first trial are falling into place.

Please find attached a brief summary of the discussion and the slides once again to refer to for both the ACTT-3 progress and the ACTG study. Please keep in mind that both of these studies are pre-FDA review so we would ask that the details not be shared broadly at this time.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

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From: Menetski, Joseph (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 5/11/2020 10:53:07 PM
To:

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Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];

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Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];

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Parker, Ashley (NIH/OD) [E]

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas /US

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Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]

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CC: Diamond, Michael; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy

b6 Hughes, Eric **b6** Jansen, Kathrin

b6 Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4b79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Kim, Elizabeth [elkim@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Wachtel, Jonathan [jwachtel@deloitte.com]; Prabhavathi Fernandes **b6** Rose Li

b6 Dana Carluccio **b6** Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D

b6

Dave Frankowski

b6

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Subject: RE: ACTIV Preclinical working group (Friday meeting)

Attachments: 2020-05-08_Preclinical_WG_Summary_D3.docx; Therapeutic information request form d1.docx; ACTIV Partnership Leadership Team Meeting 20200506 FINAL.pdf; 2020-05-06_ACTIV_Leadership_Group_Meeting_Summary FINAL.pdf

Dear Preclinical Working group members and invitees,

Attached please find the minutes from Friday's meeting for your review. If you find any mistakes, please let me know.

As part of the action items, Michael Diamond and I we tasked with drafting a 1-2 page document with information for prioritization of preclinical therapies for the expert panel to use. I have attached a first draft of what that, and have formatted it in a way that we might be able to use to collect the information from potential therapy sponsors. This actually contains info from animal (and can have anything about clinical data if repurposing). Your thoughts and suggestions about that will be helpful also.

Finally, I am attaching the slides and the minutes from the Leadership Team Meeting on 5/6/2020 for your review.

Best regards,
Joe

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T]

Sent: Tuesday, April 14, 2020 6:48 PM

To: [REDACTED] Menetski, Joseph (FNIH) [T];

b6

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Parker, Ashley (NIH/OD) [E]; Collins, Francis

(NIH/OD) [E]; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas /US; Anderson, James (NIH/OD) [E]

Cc: Diamond, Michael; Florence, Clint (NIH/NIAID) [E]; Wholley, David (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Lowy, Douglas (NIH/NCI) [E]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; [REDACTED]

b6

Subject: ACTIV Preclinical working group (Friday meeting)

When: Friday, May 8, 2020 11:00 AM-12:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: [REDACTED]

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Sent: 5/12/2020 12:29:00 PM
To: Eric Hughes [b6] Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [b6]; Keith Gottesdiener [b6]; Elliott Levy [b6]; Wung, Peter /US [b6]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [b6]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: Additional Information on Material for ACTIV TX-Clinical Agent Prioritization Subgroup #9
Attachments: ACTIV_Therapeutics Clinical Agent Prioritization Sub Group_12May2020 Meeting Guide.pdf; ACTIV Therapeutics Clinical_Agent Prioritization Sub-Group 12May2020 Mtg Agenda.pdf; Notes on [b4] in COVID Testing 051120.pdf

Dear TX-Clinical Agent Prioritization Subgroup,

In addition to the materials provided yesterday, I wanted to provide you this short description for the rational of using IL-6 inhibition in general in COVID-19 and one final point that I have been made aware of on Actemra.

RATIONALE FOR STUDYING IL-6 TREATMENT IN COVID-19 PNEUMONIA

MECHANISM OF ACTION

The pro-inflammatory, multifunctional cytokine IL-6 is produced by a variety of cell types including T cells, B cells, monocytes, fibroblasts, keratinocytes, and synovial and endothelial cells, leading to local production of IL-6 in joints affected by inflammatory processes such as rheumatoid arthritis (RA) and systemic sclerosis (SSc). It has been shown to be involved in diverse physiological processes, such as T-cell activation, B-cell differentiation, induction of immunoglobulin secretion, acute-phase protein production, stimulation of hematopoietic precursor cell growth and differentiation, osteoclast differentiation from precursor cells,

proliferation of hepatic, dermal, and neural cells, and bone and lipid metabolism (Dayer and Choy 2010). It exerts its effects through IL-6R, which is present both in soluble and in membrane-expressed forms.

Two distinct subphenotypes, a hypo-inflammatory (class 1) and hyper-inflammatory subphenotype (class 2), have been identified in acute respiratory distress syndrome (ARDS), a common and frequently fatal cause of respiratory failure among critically ill patients. The hyper-inflammatory subphenotype has higher values of sTNFr-1 and IL-6, lower platelet counts and more vasopressor use. In a 539 patient study investigating the treatment of simvastatin vs placebo, the hyper-inflammatory subphenotype had a higher mortality, fewer ventilator-free and organ failure-free days. (Calfee et al 2018 and Calfee et al. 2014). IL-6 could be a characteristic of an "inflammatory endotype" of ARDS and potentially could be target for the treatment of severe and critical COVID-19.

GM-CSF and IL-6 are the key cytokines leading to inflammatory storm which may result in increased alveolar-capillary blood-gas exchange dysfunction, especially impaired oxygen diffusion, and eventually lead to pulmonary fibrosis and organ failure. Their research suggests that IL-6 might play a key role in this process and interfering of IL-6 might be a potentially therapeutic for severe and critical COVID-19.

NOTE: Actemra (TCZ) is the only IL-6 blocker approved for the treatment of CAR-T related cytokine release syndrome.

Thanks again for your consideration of this request.

Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] | Mobile: [b6]

From: Adam, Stacey (FNIH) [T]
Sent: Monday, May 11, 2020 10:33 PM
Subject: Material for ACTIV TX-Clinical Agent Prioritization Subgroup #9

Dear TX-Clinical Agent Prioritization Subgroup,

We are looking forward to our meeting with you all tomorrow. For the meeting tomorrow, we have to goals:

1. We would like to get your feedback on the updated design for the prioritization criteria, weighting, and staging. The new model, which we have still tried to keep simple so has not to overcomplicate the process can be found in the slides for your review.
2. We will be considering an request from one of the ACTIV participating companies. There has been a request that ACTIV consider aiding with accrual to one of the IL-6 Inhibitor (Actemra) studies from Roche. This request has been made because the company has seen a recent decline in accrual due to a slowing of COVID cases in the US and due to a number of competing studies. While no promises have been made, the ACTIV Leadership did ask this team to consider the request. Upon review of the request, the co-chairs felt it was right for us to consider for the following reasons:
 - During our initial discussions, our group found IL-6 inhibitors to be a high priority target, but triaged them from our study due to the fact that we thought other well-designed trials were being conducted. Since this may no longer be the case, we wished to reconsider how we might facilitate this high priority target.

- It will benefit patients if we can get at least one of the larger trials in this class to completion so the data can be reviewed by the FDA. If determined to be a valid treatment for COVID-19, this would give us one more option for treatment.
- The company was willing to let us review the portfolio of all of the IL-6 inhibitors being tested, and only say yes to assisting them if we thought that Actemra was the best option for patients and getting a valuable treatment to them quickly.

To assist this group with this last point, I have put together a very quick summary of either the existing clinical data or preclinical data for one and links to the safety and DDI profiles for each compound. I am hoping that this will aide in your deliberations I this matter. (see attached document) We will also be receiving additional rationale information.

It is important to note that Roche is not asking for any funding, but merely help in identifying sites that would be capable of opening their trial to accelerate its accrual. If our group determines that Actemra is the most appropriate choice of IL-6 inhibitors and that IL-6 inhibition remains a high priority target, we will refer Roche to our Clinical Trial Capacity WG to have them assist in site identification.

One note: We do understand that if we choose to do this we will be putting one more trial in the same space as our master protocol, so that should likely be factored into the discussion.

Thank you all in advance for your consideration of these two topics. We look forward to a fruitful discussion tomorrow.

Best,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

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From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
Sent: 5/12/2020 1:13:04 PM
To: Bascles, Lionel [b6]; Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [b6]; Desrosiers, Betsy [b6]; Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshov, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshovj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; King, James (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce1f3853e43d4463a04f7d74992f96ac-James.King.]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura [b6]; Srinivasan, Badhri [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Vincent, Mike [b6]; Garner, Carlos [b6]; Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]
CC: Wachtel, Jonathan [jwachtel@deloitte.com]
Subject: RE: ACTIV Clinical Trial Capacity Working Group - reporting meeting
Attachments: Clinical Trial Capacity Working Group Meeting Agenda_05122020.pdf

Dear Colleagues,

Just a quick reminder that our working group meeting today (Tuesday, May 12) is scheduled for 11:00 am (eastern time USA). On Friday, we will resume our usual WG meeting time. Apologies for any confusion this has caused.

Looking forward to talking with you soon.

Karen

-----Original Appointment-----

From: Tountas, Karen (FNIH) [T]
Sent: Tuesday, April 14, 2020 5:00 PM
To: **Subject:** ACTIV Clinical Trial Capacity Working Group - reporting meeting
When: Tuesday, May 12, 2020 11:00 AM-12:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: [b6]
Importance: High

Apologies for the repeat emails, updated agenda is attached. Karen

Dear Colleagues, Attached is the meeting agenda. Looking forward to a robust discussion about vaccine protocols and capacity needs! Karen

APAR0000006520-2441937

ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines

Dear Clinical Trial Capacity Working Group members,

In anticipation of this working group making rapid progress on identified action items and other activities, the co-chairs have agreed that it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify areas of need, and to determine next steps. We ask that you make every effort possible to join each of these meetings, but understand that at times you may have competing priorities. To place a hold on your calendar, please accept this meeting invite with a response; later you can decline an individual meeting if you have a conflict.

An agenda and other meeting materials, as needed, will be distributed prior to each call.

With best regards,
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/12/2020 1:41:05 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [b6]; Eisner, Mark [b6]; Gottesdiener, Keith [b6]; Hughes, Eric [b6]; Judy Carrier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; LaVange, Lisa [b6]; Levy, Elliot [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [b6]; Patel, Naimish [b6]; Peppercorn, Amanda [b6]; Poole, Mike [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Amanda Peppercorn [b6]; Garner, Carl [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Burgess, Timothy [b6]
CC: Kim, Elizabeth [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Letter to the ACTIV Executive Committee for Group's Review
Attachments: Proposal for ACTIV leadership-vF 051220.pdf

Dear TX-Clinical Working Group members,

Please find attached the final version of the letter that will go to the ACTIV Executive Committee shortly.

Thank you all for your review,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Adam, Stacey (FNIH) [T]
Sent: Monday, May 11, 2020 12:03 PM
Subject: Letter to the ACTIV Executive Committee for Group's Review

Dear TX-Clinical Working Group members,

As discussed on last Thursday's call, the small writing team (Carl, Keith, Amanda, Judy, Libby, and Peter) have worked with the co-chairs to formulate the attached letter that attempted to capture the challenges and concerns that were expressed by the group.

They would now like to have the group review and comment if desired before the note is sent to the ACTIV Executive Committee tomorrow ahead of their scheduled meeting on Wednesday this week. **Therefore, we would ask the group to review and send any comments they have or any edits they think absolutely critical by 9AM tomorrow (May 12).** Any necessary updates will be made and then the letter will be sent on to the Executive Committee.

The team would also like to send this on behalf of the whole group with all the group members listed. **Please let us know if you are okay with this plan.**

Thank you all for your efforts and strong desire to see our remit for this partnership succeed!

Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health
Direct: b6 Mobile: b6
fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 5/12/2020 2:45:37 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Stoffels, Paul [JJCUS] [E] [b6] Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Pao, William [b6] Dolsten, Mikael [b6]
CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [b6] Hughes, Eric [b6] Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Jansen, Kathrin [b6] Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Young, John [b6] Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
Subject: FW: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group
Attachments: Proposal for ACTIV leadership-vF 051220.pdf

Dear ACTIV Executive Committee Members:

Please see the attached letter from the ACTIV Therapeutics-Clinical Working Group received this morning, for consideration on tomorrow morning's Executive Committee teleconference. While we expect the proposals contained herein will be one major topic of discussion, the purpose of the meeting is to hear from all of the Working Group co-chairs (copied on this note) regarding what is working and where they may be facing challenges in ACTIV, and jointly discuss strategy moving forward.

David

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Tuesday, May 12, 2020 9:52 AM
To: Wholley, David (FNIH) [T] [b6]
Cc: Read, Sarah (NIH/NIAID) [E] [b6] Eric Hughes [b6]; Carlos O Garner [b6]; Judy Currier [b6] Keith Gottesdiener [b6]; Amanda Peppercorn [b6] Stein, Peter (FDA/CDER)

b6

Higgs, Elizabeth (NIH/NIAID) [E]

b6

elkim@deloitte.com

Subject: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

Hi David,

Please find attached a letter from the Therapeutics-Clinical Working Group to the ACTIV Executive Committee for their consideration. Overall, the letter is meant to relate some broad challenges and issues that the Therapeutics-Clinical group thinks the ACTIV PPP is facing, as well as some very specific requests for assistance from the ACTIV EC for our team.

Please relay this to the ACTIV EC for their review. Our group would welcome any feedback they have.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 5/12/2020 2:58:32 PM
To: Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabca2247548e596778304f781f-austinc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [b6] Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Dolsten, Mikael [b6] Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Hudson, Thomas [b6] James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Johnson, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Kramer, Lynn [b6] Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffb9ae95d631116f3-marstonhd]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Meeker, David [b6] Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Pangalos, Mene [b6] Pao, William [b6] Paul, Steve [b6] Perlmutter, Roger [b6] Plump, Andy [b6] Rasi, Guido [b6] Reed, John [b6] Rouse, Doris [b6] Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Skovronsky, Daniel [b6] Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Stoffels, Paul [b6] Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Tsai, John [john.tsai@novartis.com]; Vessey, Rupert [b6] Virgin, Skip [b6] Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Young, John [b6] Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [b6] Hughes, Eric [b6] Jansen, Kathrin [b6] Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa [rosalvarez@deloitte.com]; Anderson, Margaret [marganderson@deloitte.com]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Kim, Elizabeth [elkim@deloitte.com]; Stratton, Ben [bstratton@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan

[jwachtel@deloitte.com]; Rachel Ramoni [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d3f6cb5237a44b75887b8a1ca1f9bb91-Rachel.Ramo]; Plenge, Robert [b6]; [b6]; Cavaleri, Marco [b6]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh];

CC: Barasch, Kimberly (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Conrad, Patricia (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Hoffstetter, Renata (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e9758570bf4ca08552ea377170ec2a-hoffstetter]; Iberdemaj, Vaide [b6]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Protasiewicz, Ann [b6]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; FNIH Central Account [FNIH@roseliassociates.com]; Li, Rose [b6]; Zottoli, Jessica [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Gladman, Jordan (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eb38a598f96f488299a655a7312138fd-gladmanjt]; Elsaid, Olivia [oelsaid@deloitte.com]; Castillejos zenteno, Carlos [JRDUS] [b6]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]

Subject: ACTIV Response Partnership Leadership Team Meeting #4

Location: [b6]

Start: 6/3/2020 4:00:00 PM

End: 6/3/2020 5:30:00 PM

Show Time As: Tentative

Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Collins, Francis (NIH/OD) [E]; Corey, Larry; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeling, Emily (NIH/NIAID) [E]; Fauci, Anthony (NIH/NIAID) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Pangalos, Mene; Pao, William; Paul, Steve; Perlmutter, Roger; Plump, Andy; Rasi, Guido; Reed, John; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Tsai, John; Vessey, Rupert; Virgin, Skip; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Freire, Maria (FNIH) [T]; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Gonzalez,

Nina; Kim, Elizabeth; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Rachel Ramoni; Plenge, Robert; Talley, Michael; william.lee@gilead.com; Cavaleri, Marco; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Gibbons, Gary (NIH/NHLBI) [E]

Optional Attendees: Barasch, Kimberly (NIH/NIAID) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Conrad, Patricia (NIH/NIAID) [E]; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Lagos, Enrique (NIH/NCATS) [E]; McManus, Ayanna (NIH/OD) [E]; Melencio, Cheryl (FNIH) [T]; Protasiewicz, Ann; Simon, Dina (NIH/OD) [C]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Sepulveda, Dorina (FNIH) [T]; FNIH Central Account; Li, Rose; Zottoli, Jessica; Parker, Ashley (NIH/OD) [E]; Gladman, Jordan (NIH/OD) [E]; Elsaid, Olivia; Castillejos zenteno, Carlos [JRDUS]; Dimishkov, Roxanne (NIH/NHLBI) [C]

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 5/12/2020 3:09:00 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Dolsten, Mikael [b6]; Fauci, Anthony (NIH/NIAID) [E] [b6]; Gibbons, Gary (NIH/NHLBI) [E] [b6]; Pao, William [b6]; Stoffels, Paul [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Colvis, Christine (NIH/NCATS) [E] [b6]; Desrosiers, Betsy [b6]; Hughes, Eric [b6]; Jansen, Kathrin [b6]; Kurilla, Michael (NIH/NCATS) [E] [b6]; Lowy, Douglas (NCI) [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Young, John [b6]; Freire, Maria (FNIH) [T] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Culp, Michelle (NIH/OD) [E] [b6]; Disbrow, Gary (OS/ASPR/BARDA) [b6]; Marks, Peter (FDA/CBER) [b6]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]
CC: Adam, Stacey (FNIH) [T] [b6]; Alvarez, Rosa [rosalvarez@deloitte.com]; Anderson, Margaret [marganderson@deloitte.com]; Elsaid, Olivia [oelsaid@deloitte.com]; Gonzalez, Nina [ningonzalez@deloitte.com]; James, Stephanie (FNIH) [T] [b6]; Kim, Elizabeth [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]; Stratton, Ben [bstratton@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Tountas, Karen (FNIH) [T] [b6]; Wachtel, Jonathan [jwachtel@deloitte.com]; Barasch, Kimberly (NIH/NIAID) [C] [b6]; Conrad, Patricia (NIH/NIAID) [E] [b6]; Dimishkov, Roxanne (NIH/NHLBI) [C] [b6]; McManus, Ayanna (NIH/OD) [E] [b6]; Protasiewicz, Ann [b6]; Thomas, Ashley (FDA/CDER) [b6]; Wood, Gretchen (NIH/OD) [E] [b6]; Zanellato, Ann [b6]; Burrus-Shaw, Cyndi (NIH/OD) [E] [b6]; Simon, Dina (NIH/OD) [C] [b6]; Li, Rose [b6]; FNIH Central Account [FNIH@rosellassociates.com]; Awwad, David (NIH/NIAID) [C] [b6]; Zottoli, Jessica [b6]; Togashi, Mieko (NIH/NCI) [E] [b6]; Sepulveda, Dorina (FNIH) [T] [b6]; Hardesty, Rebecca (NIH/OD) [C] [b6]; Lagos, Enrique (NIH/NCATS) [E] [b6]; Carver, Trea (NIH) [C] [b6]; Lowy, Douglas (NIH/NCI) [E] [b6]
Subject: ACTIV Executive Committee Teleconference
Location: [b6]

Start: 5/20/2020 7:30:00 PM
End: 5/20/2020 9:00:00 PM
Show Time As: Busy

Required Attendees: Collins, Francis (NIH/OD) [E]; Dolsten, Mikael; Fauci, Anthony (NIH/NIAID) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Pao, William; Stoffels, Paul; Woodcock, Janet (FDA/CDER); Tabak, Lawrence (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Freire, Maria (FNIH) [T]; Wolinetz, Carrie (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]; Anderson, James (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Marks, Peter (FDA/CBER)

Optional Attendees: Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Elsaid, Olivia; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Kim, Elizabeth; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Protasiewicz, Ann; Thomas, Ashley (FDA/CDER); Wood,

Gretchen (NIH/OD) [E]; Zanellato, Ann; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Li, Rose; FNIH Central Account; Awwad, David (NIH/NIAID) [C]; Zottoli, Jessica; Togashi, Mieko (NIH/NCI) [E]; Sepulveda, Dorina (FNIH) [T]; Hardesty, Rebecca (NIH/OD) [C]; Lagos, Enrique (NIH/NCATS) [E]; Carver, Trea (NIH) [C]; Lowy, Douglas (NIH/NCI) [E]; **b6**

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 5/12/2020 3:09:01 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Dolsten, Mikael [b6]; Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Pao, William [b6]; Stoffels, Paul [b6]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [b6]; Hughes, Eric [b6]; Jansen, Kathrin [b6]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [b6]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd42247548e596778304f781f-austinc]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa [rosalvarez@deloitte.com]; Anderson, Margaret [marganderson@deloitte.com]; Elsaid, Olivia [oelsaid@deloitte.com]; Gonzalez, Nina [ningonzalez@deloitte.com]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Kim, Elizabeth [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskij]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Stratton, Ben

[bstratton@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Tountas, Karen (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan
 [jwachtel@deloitte.com]; Barasch, Kimberly (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Conrad, Patricia
 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Dimishkov, Roxanne
 (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; McManus, Ayanna
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Protasiewicz, Ann
 [b6]; Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Zanellato, Ann
 [b6]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Li, Rose
 [b6]; FNIH Central Account [FNIH@roseliassociates.com]; Awwad, David (NIH/NIAID) [C]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0a5171ce4c4d4110abfe9aebfbdafbe7-dawwad]; Zottoli, Jessica
 [b6]; Togashi, Mieko (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togashim]; Sepulveda, Dorina (FNIH)
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Hardesty, Rebecca
 (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=21465ceb763947408d209aaabf10af70-hardestyrs]; Lagos, Enrique
 (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Carver, Trea (NIH) [C]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Lowy, Douglas (NIH/NCI)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowydw];
 [b6]

Subject: ACTIV Executive Committee Teleconference

Attachments: FW: Materials for May 20 ACTIV Executive Committee Teleconference; ACTIV mAb Meeting with Companies

Location: [b6]

Start: 5/20/2020 7:30:00 PM

End: 5/20/2020 9:00:00 PM

Show Time As: Busy

Required Attendees: Collins, Francis (NIH/OD) [E]; Dolsten, Mikael; Fauci, Anthony (NIH/NIAID) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Pao, William; Stoffels, Paul; Woodcock, Janet (FDA/CDER); Tabak, Lawrence (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Freire, Maria (FNIH) [T]; Wolinetz, Carrie (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]; Anderson, James (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Marks, Peter (FDA/CBER)

Optional Attendees: Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Elsaid, Olivia; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Kim, Elizabeth; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Protasiewicz, Ann; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Zanellato, Ann; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Li, Rose; FNIH

Central Account; Awwad, David (NIH/NIAID) [C]; Zottoli, Jessica; Togashi, Mieko (NIH/NCI) [E]; Sepulveda, Dorina (FNIH) [T]; Hardesty, Rebecca (NIH/OD) [C]; Lagos, Enrique (NIH/NCATS) [E]; Carver, Trea (NIH) [C]; Lowy, Douglas (NIH/NCI) [E]; **b6**

Cheryl Melencio is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting

b6

Meeting ID: **b6**

Password: **b6**

One tap mobile

b6 US (New York)
US (Germantown)

Dial by your location

b6 US (New York)
US (Germantown)
US (Chicago)
US (San Jose)
US (San Jose)
US (Tacoma)
US (Houston)

Meeting ID: **b6**

Password: **b6**

Find your local number: **b6**

From: Woodcock, Janet [b6]
Sent: 5/12/2020 5:45:39 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group
Flag: Follow up

Will call at 5. Thanks. jw

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Tuesday, May 12, 2020 1:31 PM
To: Woodcock, Janet [b6] >
Subject: RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

5 pm? [b6] if you can. Otherwise after 7 pm is good

From: Woodcock, Janet [b6]
Sent: Tuesday, May 12, 2020 1:08 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

No have to brief higher ups. Later better. Jwv

From: Collins, Francis (NIH/OD) [E] [b6]
Date: May 12, 2020 at 12:49:32 PM EDT
To: Woodcock, Janet [b6]
Subject: RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

Yes, I would like that. Can you do 3:30?

From: Woodcock, Janet [b6]
Sent: Tuesday, May 12, 2020 11:28 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: FW: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

Can we discuss before tomorrow? jw

From: Wholley, David (FNIH) [T] [b6]
Sent: Tuesday, May 12, 2020 10:46 AM
To: Collins, Francis S (NIH) [b6]; Stoffels, Paul [JJCUS] [b6]; Fauci, Anthony S (NIH) [b6]; Gibbons, Gary H (NIH) [b6]; Woodcock, Janet [b6]; Pao, William [b6]; Dolsten, Mikael [b6]
Cc: Colvis, Christine M (NIH) [b6]; Desrosiers, Betsy [b6]; Hughes, Eric [b6]; Read, Sarah W (NIH) [b6]; Jansen, Kathrin [b6]; Kurilla, Michael G (NIH) [b6]; Lowy, Douglas R (NIH) [b6]; Young, John [b6]; Freire, Maria C (NIH) [b6]; Tabak, Lawrence A (NIH) [b6]; Lane, Henry C (NIH) [b6]; Parker, Ashley S (NIH) [b6]

b6

> Anderson, James M (NIH) **b6**; Austin, Christopher P (NIH)
Wolinetz, Carrie D (NIH) **b6**

Subject: FW: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

Dear ACTIV Executive Committee Members:

Please see the attached letter from the ACTIV Therapeutics-Clinical Working Group received this morning, for consideration on tomorrow morning's Executive Committee teleconference. While we expect the proposals contained herein will be one major topic of discussion, the purpose of the meeting is to hear from all of the Working Group co-chairs (copied on this note) regarding what is working and where they may be facing challenges in ACTIV, and jointly discuss strategy moving forward.

David

From: Adam, Stacey (FNIH) [T] **b6**

Sent: Tuesday, May 12, 2020 9:52 AM

To: Wholley, David (FNIH) [T] **b6**

Cc: Read, Sarah (NIH/NIAID) [E] **b6**; Eric Hughes **b6**; Carlos O Garner

b6; Judy Currier **b6**; Keith Gottesdiener

b6; Amanda Peppercorn **b6**; Stein, Peter (FDA/CDER)

b6; Higgs, Elizabeth (NIH/NIAID) [E]; **b6**; elkim@deloitte.com

Subject: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

Hi David,

Please find attached a letter from the Therapeutics-Clinical Working Group to the ACTIV Executive Committee for their consideration. Overall, the letter is meant to relate some broad challenges and issues that the Therapeutics-Clinical group thinks the ACTIV PPP is facing, as well as some very specific requests for assistance from the ACTIV EC for our team.

Please relay this to the ACTIV EC for their review. Our group would welcome any feedback they have.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Foundation for the National Institutes of Health

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From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 5/12/2020 6:02:20 PM
Subject: *Call with Dr. Janet Woodcock
Attachments: image001.jpg; image002.jpg; image003.jpg; image004.jpg; image005.png
Location: She will dial you on your iPhone

Start: 5/12/2020 9:00:00 PM
End: 5/12/2020 9:10:00 PM
Show Time As: Busy

Recurrence: (none)

Will call at 5. Thanks. jw

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Tuesday, May 12, 2020 1:31 PM
To: Woodcock, Janet [b6]
Subject: RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

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Date: May 12, 2020 at 12:49:32 PM EDT
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From: Woodcock, Janet [b6]
Sent: Tuesday, May 12, 2020 11:28 AM
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Subject: FW: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

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Sent: Tuesday, May 12, 2020 10:46 AM
To: Collins, Francis S (NIH) [b6]; Stoffels, Paul [JJCUS] [b6]; Fauci, Anthony S (NIH)

[b6]; Gibbons, Gary H (NIH) [b6] Woodcock, Janet
[b6]; Pao, William [b6]; Dolsten, Mikael
Cc: Colvis, Christine M (NIH) [b6]; Desrosiers, Betsy [b6] Hughes,
Eric [b6] Read, Sarah W (NIH) [b6]; Jansen, Kathrin
[b6]; Kurilla, Michael G (NIH) [b6]; Lowy, Douglas R (NIH)
[b6]; Young, John [b6]; Freire, Maria C (NIH) [b6]; Tabak,
Lawrence A (NIH) [b6] Lane, Henry C (NIH) [b6] Parker, Ashley S (NIH)
[b6]; Anderson, James M (NIH) [b6]; Austin, Christopher P (NIH)
[b6] Wolinetz, Carrie D (NIH) [b6]

Subject: FW: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

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David

From: Adam, Stacey (FNIH) [T] [b6]

Sent: Tuesday, May 12, 2020 9:52 AM

To: Wholley, David (FNIH) [T] [b6]

Cc: Read, Sarah (NIH/NIAID) [E] [b6]; Eric Hughes [b6] Carlos O Garner

[b6]; Judy Currier [b6] Keith Gottesdiener

[b6]; Amanda Peppercorn [b6] Stein, Peter (FDA/CDER)

[b6] Higgs, Elizabeth (NIH/NIAID) [E] [b6]

Subject: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

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Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Foundation for the National Institutes of Health

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 5/13/2020 1:57:04 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Dolsten, Mikael [b6]; Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Pao, William [b6]; Stoffels, Paul [JJCUS] [b6]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [b6]; Hughes, Eric [b6]; Jansen, Kathrin [b6]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [b6]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Wolf-Rodda, Julie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=89f0a08ab7224e0b9dc5a118ff336aff-wolfrodj]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]
CC: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]
Subject: Agenda for ACTIV EC meeting tomorrow morning at 8:00 AM Eastern US Time
Attachments: Agenda ACTIV EC Meeting #1 5-13-20.docx; Proposal for ACTIV leadership-vF 051220.pdf

Dear ACTIV EC members, Working Group Co-Chairs, and meeting participants:
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Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

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11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/13/2020 1:58:34 AM
To: Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [b6]; Keith Gottesdiener [b6]; Elliott Levy [b6]; Wung, Peter /US [b6]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [b6]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: Initial Follow-up from ACTIV TX-Clinical Agent Prioritization Subgroup #9
Attachments: ACTIV_Therapeutics-Clinical_AP Sub-Group Meeting 12May2020 Key Takeaways.pdf

Dear TX-Clinical Agent Prioritization Subgroup,

Thank you so much for another meeting with great feedback to refine the process. Elizabeth and I will work to incorporate your additional changes to the scoring and weighting. In addition, I am looking into the additional resources that the group was requesting.

For now please find some high level action items and notes that Elizabeth was kind enough to capture. I will follow-up with the formal summary to the meeting in the next 24 hours or so.

As always, if you have any questions, please do not hesitate to contact us.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

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Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 5/13/2020 2:03:51 AM
To: Stoffels, Paul [b6]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: FW: Agenda for ACTIV EC meeting tomorrow morning at 8:00 AM Eastern US Time
Attachments: Agenda ACTIV EC Meeting #1 5-13-20.docx; Proposal for ACTIV leadership-vF 051220.pdf

Hi Paul,

I understand from David Wholley that you will be able to join the ACTIV ExComm call tomorrow – I am really glad to have your co-leadership for this important discussion.

Can I ask you to make brief opening remarks at the outset, and also to help me summarize at the end?

Many thanks, Francis

From: Wholley, David (FNIH) [T] [b6]
Sent: Tuesday, May 12, 2020 9:57 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Dolsten, Mikael [b6]; Fauci, Anthony (NIH/NIAID) [E] [b6]; Gibbons, Gary (NIH/NHLBI) [E] [b6]; Pao, William [b6]; Stoffels, Paul [JJCUS] [b6]; Woodcock, Janet (FDA/CDER) [b6]; Colvis, Christine (NIH/NCATS) [E] [b6]; Desrosiers, Betsy [b6]; Hughes, Eric [b6]; Jansen, Kathrin [b6]; Kurilla, Michael (NIH/NCATS) [E] [b6]; Lowy, Douglas (NIH/NCI) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Young, John [b6]; Menetski, Joseph (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Wolf-Rodda, Julie (FNIH) [T] [b6]; Gonzalez, Nina <ningonzalez@deloitte.com>
Cc: Melencio, Cheryl (FNIH) [T] [b6]; Wood, Gretchen (NIH/OD) [E] [b6]
Subject: Agenda for ACTIV EC meeting tomorrow morning at 8:00 AM Eastern US Time
Importance: High

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Please let Joe Menetski or Cheryl Melencio know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/13/2020 2:37:49 AM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Coll]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [b6]; Keith Gottesdiener [b6]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Elliott Levy [b6]; Sandeep Menon [b6]; Amanda Peppercorn [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [b6]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [b6]; Wung, Peter /US [b6]; Karen Lynn Price [b6]; Pamela Tenaerts, M.D. [b6]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Burgess, Timothy [b6]; Beumont-Mauviel, Maria [JRDU] [b6]; Peeters, Monika [JRDBE] [b6]; Woodfall, Brian [JRDU] [b6]; Van Heeswijk, Rolf [JRDBE] [b6]
CC: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: Materials for ACTIV TX-Clinical Master Protocol Subgroup Meeting #16
Attachments: ACTIV Therapeutics-Clinical_MP Subgroup_13May2020 Meeting Guide.pdf

Dear TX-Clinical Master Protocol Subgroup,

Please find attached the slides for our portion of the meeting tomorrow. The presentation slides from I-SPY will be shared on the call from their group.

We are going to try to keep the I-SPY presentation to no more than 40 minutes, including questions so we can discuss a few necessary matters for next steps on our trials.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/13/2020 10:46:49 AM
To: Hardesty, Rebecca (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21465ceb763947408d209aaabf10af70-hardestyrs]
Subject: Fwd: Agenda for ACTIV EC meeting tomorrow morning at 8:00 AM Eastern US Time
Attachments: Agenda ACTIV EC Meeting #1 5-13-20.docx; ATT00001.htm; Proposal for ACTIV leadership-vF 051220.pdf; ATT00002.htm

Begin forwarded message:

From: "Wholley, David (FNIH) [T]" [b6]
Date: May 12, 2020 at 9:57:04 PM EDT
To: "Collins, Francis (NIH/OD) [E]" [b6] "Dolsten, Mikael" [b6]
[b6] "Fauci, Anthony (NIH/NIAID) [E]" [b6] "Gibbons, Gary (NIH/NHLBI) [E]" [b6] "Pao, William" [b6] "Stoffels, Paul [JJCUS]" [b6] "Woodcock, Janet (FDA/CDER)" [b6]
"Colvis, Christine (NIH/NCATS) [E]" [b6] "Desrosiers, Betsy" [b6]
[b6] "Hughes, Eric" [b6] "Jansen, Kathrin" [b6]
[b6] "Kurilla, Michael (NIH/NCATS) [E]" [b6] "Lowy, Douglas (NIH/NCI) [E]" [b6]
"Read, Sarah (NIH/NIAID) [E]" [b6]
"Young, John" [b6] "Menetski, Joseph (FNIH) [T]" [b6]
"Adam, Stacey (FNIH) [T]" [b6] "Tountas, Karen (FNIH) [T]" [b6]
"Santos, Michael (FNIH) [T]" [b6] "Freire, Maria (FNIH) [T]" [b6]
"Tabak, Lawrence (NIH/OD) [E]" [b6] "Lane, Cliff (NIH/NIAID) [E]" [b6]
[b6] "Parker, Ashley (NIH/OD) [E]" [b6] "Anderson, James (NIH/OD) [E]" [b6]
"Austin, Christopher (NIH/NCATS) [E]" [b6]
[b6] "Wolf-Rodda, Julie (FNIH) [T]" [b6] "Gonzalez, Nina" [b6]
<ningonzalez@deloitte.com>
Cc: "Melencio, Cheryl (FNIH) [T]" [b6] "Wood, Gretchen (NIH/OD) [E]" [b6]
[b6]

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Regards,

David

David Wholley
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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/13/2020 11:19:33 AM
To: Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
CC: Hardesty, Rebecca (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21465ceb763947408d209aaabf10af70-hardestyrs]
Subject: Fwd: Agenda for ACTIV EC meeting tomorrow morning at 8:00 AM Eastern US Time
Attachments: Agenda ACTIV EC Meeting #1 5-13-20.docx; ATT00001.htm; Proposal for ACTIV leadership-vF 051220.pdf; ATT00002.htm

For 8am ACTIV EC Meeting if you want to read ahead.

Thanks,
Ashley

Begin forwarded message:

From: "Wholley, David (FNIH) [T]" [b6]
Date: May 12, 2020 at 9:57:04 PM EDT
To: "Collins, Francis (NIH/OD) [E]" [b6], "Dolsten, Mikael" [b6], "Fauci, Anthony (NIH/NIAID) [E]" [b6], "Gibbons, Gary (NIH/NHLBI) [E]" [b6], "Pao, William" [b6], "Stoffels, Paul [JJCUS]" [b6], "Woodcock, Janet (FDA/CDER)" [b6], "Colvis, Christine (NIH/NCATS) [E]" [b6], "Desrosiers, Betsy" [b6], "Hughes, Eric" [b6], "Jansen, Kathrin" [b6], "Kurilla, Michael (NIH/NCATS) [E]" [b6], "Lowy, Douglas (NIH/NCI) [E]" [b6], "Read, Sarah (NIH/NIAID) [E]" [b6], "Young, John" [b6], "Menetski, Joseph (FNIH) [T]" [b6], "Adam, Stacey (FNIH) [T]" [b6], "Tountas, Karen (FNIH) [T]" [b6], "Santos, Michael (FNIH) [T]" [b6], "Freire, Maria (FNIH) [T]" [b6], "Tabak, Lawrence (NIH/OD) [E]" [b6], "Lane, Cliff (NIH/NIAID) [E]" [b6], "Parker, Ashley (NIH/OD) [E]" [b6], "Anderson, James (NIH/OD) [E]" [b6], "Austin, Christopher (NIH/NCATS) [E]" [b6], "Wolf-Rodda, Julie (FNIH) [T]" [b6], "Gonzalez, Nina" [b6] <ningonzalez@deloitte.com>
Cc: "Melencio, Cheryl (FNIH) [T]" [b6], "Wood, Gretchen (NIH/OD) [E]" [b6]
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Regards,

David

APAR0000013379

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Foundation for the National Institutes of Health

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11400 Rockville Pike Suite 600 North Bethesda, MD 20852

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From: Anderson, James (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=73143D1860BC42458BE254CA21573B23-ANDERSONJM]
Sent: 5/13/2020 11:23:17 AM
To: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
Subject: FW: Agenda for ACTIV EC meeting tomorrow morning at 8:00 AM Eastern US Time
Attachments: Need for NHP planning coordination process 5-12-2020.docx

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Thanks for your help.

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From: Wholley, David (FNIH) [T] [b6]
Sent: Tuesday, May 12, 2020 9:57 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Dolsten, Mikael [b6]; Fauci, Anthony (NIH/NIAID) [E] [b6]; Gibbons, Gary (NIH/NHLBI) [E] [b6]; Pao, William [b6]; Stoffels, Paul [JJCUS] [b6]; Woodcock, Janet (FDA/CDER) [b6]; Colvis, Christine (NIH/NCATS) [E] [b6]; Desrosiers, Betsy [b6]; Hughes, Eric [b6]; Jansen, Kathrin [b6]; Kurilla, Michael (NIH/NCATS) [E] [b6]; Lowy, Douglas (NIH/NCI) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Young, John [b6]; Menetski, Joseph (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Wolf-Rodda, Julie (FNIH) [T] [b6]; Gonzalez, Nina <ningonzalez@deloitte.com>
Cc: Melencio, Cheryl (FNIH) [T] [b6]; Wood, Gretchen (NIH/OD) [E] [b6]
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Importance: High

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b6

fnih.org

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Sent: 5/13/2020 11:53:26 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; NIH Director's Executive Committee [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8dd6ae9e97864c7a930aa2a27dc4cb28-OD-Small St]
CC: Prince, Scott (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0fd557b0e1194e36bc407110cb681025-princes]; OCPLPressTeam [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53ba510dfce44512b4a76db41c90df84-OCPL Press]; Kolberg, Rebecca (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=30071513c5a8433a98883fd78d360a91-kolbergr]; Pelis, Kim (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d27af8a8b53f4728a25e9b83984ce9f1-pelisk]; George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]; Kuska, Bob (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9c3f44321bf44ada7bdf6ac1edcfa85-kuskar]
Subject: Science: Unveiling 'Warp Speed,' the White House's America-first push for a coronavirus vaccine

Science



AP Photo/Ted S. Warren

Unveiling 'Warp Speed,' the White House's America-first push for a coronavirus vaccine

By [Jon Cohen](#) May. 12, 2020 , 5:05 PM

Science's COVID-19 reporting is supported by the Pulitzer Center.

Conventional wisdom is that a vaccine for COVID-19 is at least 1 year away, but the organizers of a U.S. government push called Operation Warp Speed have little use for conventional wisdom. The project, vaguely described to date but likely to be formally announced by the White House in the coming days, will pick a diverse set of vaccine candidates and

pour essentially limitless resources into unprecedented comparative studies in animals, fast-tracked human trials, and manufacturing. Eschewing international cooperation—and any vaccine candidates from China—it hopes to have 300 million doses by January 2021 of a proven product, reserved for Americans.

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- [Coronavirus](#)

From: Tabak, Lawrence (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02E22836B5FF4E9988E3770CFC7EE770-TABAKL]
Sent: 5/13/2020 1:02:28 PM
To: Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
Subject: Re: Agenda for ACTIV EC meeting tomorrow morning at 8:00 AM Eastern US Time

Thanks Jim. I did speak on your behalf, emphasizing that you have connected with all primate centers and that they are onboard, but we need the exec comm guidance about priorities.

Larry

From: "Anderson, James (NIH/OD) [E]" [b6]
Date: Wednesday, May 13, 2020 at 7:25 AM
To: "Tabak, Lawrence (NIH/OD) [E]" [b6], "Colvis, Christine (NIH/NCATS) [E]" [b6], "Wholley, David (FNIH) [T]" [b6], "Menetski, Joseph (FNIH) [T]" [b6]
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Cc: Melencio, Cheryl (FNIH) [T] [b6] Wood, Gretchen (NIH/OD) [E] [b6]

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Subject: FW: Science: Unveiling 'Warp Speed,' the White House's America-first push for a coronavirus vaccine

It's really unfortunate that Jon Cohen is painting a picture of some kind of conflict or duplication between ACTIV and Operation Warp Speed. That's not the case at all. He also says that ACTIV is considering human challenge trials, which is absolutely not the case. How come Jon didn't reach out to me? b5

b5

Francis

From: Myles, Renate (NIH/OD) [E] b6
Sent: Wednesday, May 13, 2020 7:53 AM
To: Collins, Francis (NIH/OD) [E] b6; NIH Director's Executive Committee <OD-SmallStaff@mail.nih.gov>
Cc: Prince, Scott (NIH/OD) [E] b6; OCPLPressTeam <OCPLPressTeam@od.nih.gov>; Kolberg, Rebecca (NIH/OD) [E] b6; Pelis, Kim (NIH/OD) [E] b6; George, Jill (NIH/OD) [E] b6; Kuska, Bob (NIH/OD) [E] b6
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Science



AP Photo/Ted S. Warren

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By [Jon Cohen](#) May. 12, 2020 , 5:05 PM

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- [Coronavirus](#)

doi:10.1126/science.abc7056

From: Myles, Renate (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7D317F5626934585B3692A1823C1B522-MYLESR]
Sent: 5/13/2020 3:17:47 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]
CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Science: Unveiling 'Warp Speed,' the White House's America-first push for a coronavirus vaccine

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Sent: Wednesday, May 13, 2020 11:10 AM
To: Myles, Renate (NIH/OD) [E] [b6]; Burklow, John (NIH/OD) [E] [b6]
Cc: Tabak, Lawrence (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]
Wholley, David (FNIH) [T] [b6]
Subject: FW: Science: Unveiling 'Warp Speed,' the White House's America-first push for a coronavirus vaccine

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[b5]

Francis

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 7:53 AM
To: Collins, Francis (NIH/OD) [E] [b6]; NIH Director's Executive Committee <OD-SmallStaff@mail.nih.gov>
Cc: Prince, Scott (NIH/OD) [E] [b6]; OCPLPressTeam <OCPLPressTeam@od.nih.gov>; Kolberg, Rebecca (NIH/OD) [E] [b6]; Pelis, Kim (NIH/OD) [E] [b6]; George, Jill (NIH/OD) [E] [b6]; Kuska, Bob (NIH/OD) [E] [b6]
Subject: Science: Unveiling 'Warp Speed,' the White House's America-first push for a coronavirus vaccine

Science



AP Photo/Ted S. Warren

Unveiling ‘Warp Speed,’ the White House’s America-first push for a coronavirus vaccine

By [Jon Cohen](#) May. 12, 2020 , 5:05 PM

***Science’s* COVID-19 reporting is supported by the Pulitzer Center.**

Conventional wisdom is that a vaccine for COVID-19 is at least 1 year away, but the organizers of a U.S. government push called Operation Warp Speed have little use for conventional wisdom. The project, vaguely described to date but likely to be formally announced by the White House in the coming days, will pick a diverse set of vaccine candidates and pour essentially limitless resources into unprecedented comparative studies in animals, fast-tracked human trials, and manufacturing. Eschewing international cooperation—and any vaccine candidates from China—it hopes to have 300 million doses by January 2021 of a proven product, reserved for Americans.

Those and other details, spelled out for *Science* by a government official involved with Warp Speed, have unsettled some vaccine scientists and public health experts. They’re skeptical about the timeline and hope Warp Speed will complement, rather than compete with, ongoing COVID-19 vaccine efforts, including one announced last month by the National Institutes of Health (NIH). “Duplication only leads to infighting and slowing people down,” says Nicole Lurie, former U.S. assistant secretary for preparedness and response, who advises the Coalition for Epidemic Preparedness Innovations (CEPI), a nonprofit funding and helping coordinate COVID-19 vaccine efforts. “The U.S., and others around the world, should be engaged in this competition against the virus, not against one another.”

Warp Speed, first revealed by Bloomberg News on 29 April, has so far only been outlined. President Donald Trump briefly discussed the initiative the next day, saying, “We’re going to fast track it like you’ve never seen before.” According to a CNN report on 1 May, which the source who spoke to *Science* confirmed, Warp Speed intends to deliver the first 100 million doses of a vaccine in November and another 200 million over the following 2 months.

An extraordinary 110 COVID-19 vaccines are in development, and eight candidates—four from Chinese companies—have entered small trials in people, according to an 11 May update from the World Health Organization (WHO). But there’s less than meets the eye in many of the efforts, says a vaccine veteran who asked not to be named. “Half of them are companies that have three guys, an administrative assistant, and a dog.”

The idea for Warp Speed was hatched in early April, says the official, a scientist, who was given permission to discuss it with *Science* if his name was not used. “Looking around, it became clear that without a really heroic effort, none of the

existing efforts to produce vaccine was going to lead us to have vaccine to prevent what looks increasingly like a second wave that could sweep come October, November,” he says. Warp Speed will have three separate “virtual teams” to address development, supply and manufacturing, and distribution, led by a “core team” of a few dozen experts from government, industry, and academia.

Warp Speed has already narrowed its list of vaccine candidates to 14 and plans to push ahead with eight, the official says. “The idea for us is to pick a diversified portfolio” of vaccines made with different technologies, or platforms. Organizers were concerned that other government vaccine investment has been “heavily weighted” toward just two candidates: one made with messenger RNA encoding the coronavirus surface “spike” protein and the other using a cold-causing adenovirus to deliver the same protein’s gene. Neither technology, the official notes, has yet led to approved vaccines for any disease.

The official declined to identify Warp Speed’s vaccine candidates, but he stressed two key criteria: safety and the potential to make hundreds of millions of doses quickly. “We don’t have time to debug manufacturing issues here,” he says. By July, Warp Speed hopes to have its eight lead candidates in human trials. At the same time, it will fund a large-scale comparison of their safety and efficacy in hamsters and monkeys to help winnow down that group. “If something’s really bad, we’ll get rid of it,” he says.

In parallel with the trials, the project will lay the groundwork for “heavy duty manufacturing” of as many as four different vaccines. More than one may prove worthy, and multiple options guard against contamination incidents and other supply concerns.

Although Warp Speed has not ruled out any type of vaccine, it will not consider ones made in China, such as the inactivated virus vaccine recently shown to protect monkeys from the coronavirus, a first. “We can’t partner with Chinese companies,” the official says. “That’s just not going to happen.” The decision was “above my pay grade,” he adds. But the chosen vaccines could be made by a company that is not headquartered in the United States. (White House trade adviser Peter Navarro in a February memo to the Coronavirus Task Force championed a “Manhattan Project” for COVID-19 vaccines that would prioritize U.S.-based companies.)

Warp Speed’s main goal is to protect the United States. “The attitude here is the oxygen mask approach,” the official says. “We want to get our oxygen mask on first and then we’re going to help the people around us.” Warp Speed, he says, plans to “freely disseminate information” to other countries and share manufacturing technologies, and it may make extra doses for the world.

Many scientists and organizations have argued, however, that any proven COVID-19 vaccines should be accessible and affordable to everyone in the world at the same time. WHO and other groups on 24 April formed the Access to COVID-19 Tools Accelerator that aims to speed development of diagnostics, therapeutics, and vaccines, and ensure “equitable global access to safe, quality, effective, and affordable” products. The European Commission, in turn, organized a fundraiser on 4 May, the Coronavirus Global Response, at which world leaders from many countries and some philanthropists pledged \$8 billion; the United States did not participate. CEPI and another nonprofit group, GAVI, the Vaccine Alliance, will oversee the vaccine drive. “It’s a global problem, and it needs a global solution,” says Seth Berkley, who heads GAVI.

Berkley supports Warp Speed’s plan to triage the many candidates, but he calls it a shortsighted mistake to rule out Chinese products, “given the fact that they’re a couple of months ahead.” The Bill & Melinda Gates Foundation is closely following “15 or so” vaccine candidates, including ones from China, and will support the most promising ones, adds Emilio Emini, a former vaccine developer now with the foundation. “You need to have a global portfolio so that you’re not putting all your chips on one part of the roulette table,” he says.

WHO has yet another ambitious COVID-19 vaccine project, the Solidarity Trial, that plans to compare candidates in human studies. That effort is headed by Andrew Witty, former CEO of GlaxoSmithKline, a major vaccine manufacturer. On Monday, WHO Director-General Tedros Adhanom Ghebreyesus said there are seven or eight “top” vaccine

candidates the group hopes to accelerate. What will happen with production and supply if one of these other groups and Warp Speed select the same vaccine to prioritize is unknown.

Warp Speed's relationship to the NIH initiative, Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV), remains unclear. That project plans to coordinate clinical trials of several COVID-19 vaccines and use common institutional review boards, safety monitors, and protocols, NIH Director Francis Collins and co-authors explain in a commentary published online on 11 May by *Science*. ACTIV is also considering controversial human "challenge" studies, which would fast-track a vaccine's evaluation by immunizing healthy people and deliberately infecting them with the new coronavirus or a weakened form of it.

When asked about the NIH effort, the Warp Speed official said there is "no conflict at all—they are working together—one intellectually (ACTIV) and one operationally (Warp Speed)." But several scientists on the ACTIV vaccine subcommittee say they know little about Warp Speed. And one member, Peter Hotez of the Baylor College of Medicine, worries about both its name and timeline, noting the antivaccine movement argues products are often rushed to market without adequate testing. "Some of the language coming out of the White House is very damaging," says Hotez, who is part of a team making a COVID-19 vaccine candidate. As for the January delivery of 300 million doses, "I don't see a path by which you can collect enough efficacy and safety data by the end of the year."

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To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]
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Subject: RE: Science: Unveiling 'Warp Speed,' the White House's America-first push for a coronavirus vaccine

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From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 11:18 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Burklow, John (NIH/OD) [E] [b6]
Cc: Tabak, Lawrence (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]
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To: Collins, Francis (NIH/OD) [E] [b6]; NIH Director's Executive Committee <OD-SmallStaff@mail.nih.gov>
Cc: Prince, Scott (NIH/OD) [E] [b6]; OCPLPressTeam <OCPLPressTeam@od.nih.gov>; Kolberg, Rebecca (NIH/OD) [E] [b6]; Pelis, Kim (NIH/OD) [E] [b6]; George, Jill (NIH/OD) [E] [b6]; Kuska, Bob (NIH/OD) [E] [b6]
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AP Photo/Ted S. Warren

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
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To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [b6]; Eisner, Mark [b6]; Gottesdiener, Keith [b6]; Hughes, Eric [b6]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [elkim@deloitte.com]; LaVange, Lisa [b6]; Levy, Elliot [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [b6]; Peppercorn, Amanda [b6]; Poole, Mike [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coll]; Amanda Peppercorn [b6]; Garner, Carl [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Burgess, Timothy [b6]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]
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 [jwachtel@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Alvarez, Rosa [rosalvarez@deloitte.com];
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 Li Central Account [FNIH@roseliassociates.com]; Anderson, Margaret [marganderson@deloitte.com]; Lucas
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 [b6]; Mollica, Linda /US [b6]; Qashu, Felicia (NIH/OD) [E]
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Subject: Materials for ACTIV TX-Clinical Working Group #6

Attachments: FDA Guidance on COVID Trials.pdf; ACTIV Therapeutics-Clinical Full Working Group_14May2020 Meeting Guide.pdf

Dear TX-Clinical Working Group,

Please find attached the slides for tomorrow's call to help facilitate our report outs from both groups. If you have any additions or amendments to propose, please send them to me.

The co-chairs will be updating the group on the ACTIV Executive Committee's feedback and promised actions in response to our letter. This will include some immediate next steps for our group on the mAbs master protocol discussion. Thank you all once again for this feedback to the leadership. It was well received, and it looks like will elicit immediate action on some of the requests.

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Looking forward to tomorrow's call.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

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 [b6] Mollica, Linda /US [b6] Qashu, Felicia (NIH/OD) [E]
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Subject: ACTIV TX-Clinical Working Group #6

Attachments: FDA Guidance on COVID Trials.pdf; ACTIV Therapeutics-Clinical Full Working Group_14May2020 Meeting Guide.pdf

Location: [b6]

Start: 5/14/2020 6:00:00 PM

End: 5/14/2020 7:00:00 PM

Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]

Optional Attendees: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; [b6] Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] [b6]

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Looking forward to tomorrow's call.

Thanks,
Stacey

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CC: Criffield, Robin [b6]; Hamilton, Nancy [b6]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Minnich, Beth [b6]; Mueller-Reichenstein, Petra [b6]; Pico, Dianna (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=471cb6a63c8846a69073e1e968f3964c-picodf]; Quadros, Nora [b6]; Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Hill, Zoe (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [b6]; Jansen, Kathrin [b6]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [b6]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [marganderson@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Carluccio, Dana [b6]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny [b6]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [b6]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative

Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveesson, Nancy [redacted] b6; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]

Subject: Summary and action items - CT Capacity WG meeting #8

Attachments: Clinical_Trial_Capacity_Working_Group_Meeting 8_Summary_Final.pdf

Dear Clinical Trial Capacity Working Group Members,

Attached is the summary and action items for meeting #8 (May 12, 2020) of the full working group. The next full working group meeting is scheduled for Friday, May 15 at 9 am eastern time USA. Looking forward to it!

Kind regards,
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health

[redacted] b6 fniih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bafd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Dana Carluccio [b6]; Rose Li Central Account [FNIH@roseliassociates.com]
Subject: Materials for the ACTIV TX-Clinical Agent Prioritization Subgroup #10
Attachments: IL-6 Trial Information.pdf; ACTIV_Therapeutics Clinical Agent Prioritization Sub Group_14May2020 Meeting Guide.pdf; Therapeutic information request form-v4.docx

Dear ACTIV TX-Clinical Agent Prioritization Subgroup,

Please find attached the materials for tomorrow's call. We will use them to follow up on our conversations from Tuesday, and well as discuss next steps.

The materials include:

1. Meeting slides for tomorrow, which have both the updated Agent Prioritization Criteria and Weighted Scoring Rubric for your review. **Please take a look and see if Elizabeth and I captured all your thoughts from Tuesday.**
2. Slides with Status of IL-6 trials for three agents in the clinic. **Please take a look at these slides and see if this is the type of snapshot information you have wanted to be able to pull for any given agent as you review.** While I know there is some desirable information missing, such as RCT vs. uncontrolled trial, if it looks good, feel free to play around a bit more with the tracker from Oxford that I pulled the data from: http://covid19.trialstracker.net/data_viz.html. What I am hoping to understand is if there are publicly available sites that can help fill our data aggregation needs until we can potentially get access to others that maybe more comprehensive. For comparison to the Oxford site, you can check out the Cytel site which maps the trials to given countries, but only shows intended accrual and not current accrual like the Oxford site: <https://covid19->

[trials.com/](https://www.clinicaltrials.com/). The challenge is likely that we may need a couple sites to fulfill the information that we need, but it would prevent us from reinventing the wheel that other maybe creating already. I will continue exploring options, but thanks for reviewing.

3. Finally, as discussed on Tuesday, the preclinical group and our team have worked to put together a first version of the company survey/RFI that we would use for multiple purposes: 1) to do specific information solicitation on high priority compounds that this group wishes to score, 2) to have any company or group who has submitted an agent for your consideration populate this so we are working on the right data, and 3) potentially to do a broad company solicitation of additional compounds that the companies would like to have considered for testing.

Please review and let us know if this has all the questions you would want to see to ensure that we will have the right data to review for our high priority compounds. We have worked to balance being thorough with making sure it is not too onerous for a company to fill out. **Please let us know if you have any amendments or additions.**

Thank you for your review of these materials. We look forward to a productive call tomorrow.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
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CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bafd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Dana Carluccio [b6]; Rose Li Central Account [FNIH@roseliassociates.com]
Subject: ACTIV TX-Clinical Agent Prioritization Subgroup #10
Attachments: IL-6 Trial Information.pdf; ACTIV_Therapeutics Clinical Agent Prioritization Sub Group_14May2020 Meeting Guide.pdf; Therapeutic information request form-v4.docx
Location: [b6]
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Required Attendees: Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E]
Optional Attendees: Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; [b6]; Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] [b6]; Dana Carluccio; Rose Li Central Account

Dear ACTIV TX-Clinical Agent Prioritization Subgroup,

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Thank you for your review of these materials. We look forward to a productive call tomorrow.

Thanks,
Stacey

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Subject: RE: JAMA Viewpoint on ACTIV: please review
Attachments: Master and WG Email List for ACTIV rv 05042020_cm.xlsx

Here is what Cheryl provided as of Friday – she may have additional updates.

Vaccines:

Annunziato, Paula [b6]
Arvin, Ann [b6]
Buchbinder, Susan [b6]
Corey, Larry [b6]
Davis, Mark [b6]
Emini, Emilio [b6]
Hanon, Emmanuel [b6]
Haynes, Barton [b6]
Hotez, Peter [b6]
Jansen, Kathrin [b6]
Lanzavecchia, Antonio [b6]
Lowy, Douglas (NIH/NCI) [E] [b6]
Marks, Peter (FDA/CBER) [b6]
Mascola, John [b6]
Messonnier, Nancy (CDC/DDID/NCIRD/OD) [b6]
Offit, Paul [b6]
Parker, Ashley (NIH/OD) [E] [b6]
Santos, Michael (FNIH) [b6]
Santos, Nancy [b6]
Schuitemaker, Hanneke [b6]
Tartaglia, Jim [b6]
[b6]
Zaks, Tal [b6]
Qashu, Felicia [b6]
Michael, Nelson [b6]

Clinical Capacity

Adam, Stacey (FNIH) [T] [b6]
Bascles, Lionel [b6]
Cohen, Myron [b6]
Corey, Larry [b6]
Desrosiers, Betsy [b6]
Dickens, Jim (NIH/NCATS) [C] [b6]
Doroshov, James (NIH/NCI) [E] [b6]
Goff, David (NIH/NHLBI) [E] [b6]
Heaton, Penny [b6]

Kurilla, Mike [b6]
Nayak, Seema (NIH/NIAID) [E] [b6]
Parker, Ashley (NIH/OD) [E] [b6]
Payton, Manzine [b6]
Resnansky, Laura [b6]
Srinivasan, Badhri [b6]
Stein, Peter (FDA/CDER) [b6]
Tountas, Karen (FNIH) [T] [b6]
Vincent, Mike [b6]
Wachtel, Jonathan [b6]
Woodcock, Janet (FDA/CDER)

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Qashu, Felicia<felicia.qashu@nih.gov>

Preclinical

Adams, Peter (OS/ASPR/BARDA) [b6]
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Anderson, Annaliesa [b6]
Baric, Ralph [b6]
Carter, Kara [b6]
Colvis, Christine [b6]
Deming, Damon (FDA/CDER) [b6]
Diamond, Michael [b6]
Duncan, Ken [b6]
Fernandes, Prabhavathi [b6]
Gatto, Greg [b6]
Grobler, Jay [b6]
Hewitt, Judith [b6]
Jonson, Samantha (NIH/NCATS) [E]
[b6]
Lutz, Cat [b6]
Menetski, Joseph (FNIH) [T] [b6]
Nestle, Frank [b6]
Ottinger, Liz [b6]
Parker, Ashley (NIH/OD) [E] [b6]
Payne, David [b6]
Rao, Srinivasa [b6]
Rappaport, Jay [b6]
Stegmeier, Frank [b6]
Young, John [b6]
Qashu, Felicia< [b6]
Pitt, Louise [b6]
Cihlar, Tomas [b6]

Tx Clinical

Adam, Stacey (FNIH) [T] [b6]
Bozzette, Sam (NIH/NCATS) [E] [b6]

Buchman, Tim (OS/ASPR/BARDA) (CTR) [b6]
Butterton, Joan [b6]
Currier, Judy [b6]
De Claro, R. Angelo (FDA/CDER) [b6]
Draghia-Akli, Ruxandra [b6]
Eisner, Mark [b6]
Garner, Carlos [b6]
Gottesdiener, Keith [b6]
Hughes, Eric [b6]
Kim, Elizabeth [b6]
LaVange, Lisa [b6]
Levy, Elliot [b6]
Mellors, John [b6]
Menon, Sandeep [b6]
Parker, Ashley (NIH/OD) [E] [b6]
Patel, Naimish [b6]
Peppercorn, Amanda [b6]
Poole, Mike [b6]
Proschan, Michael [b6]
Read, Sarah [b6]
Santos, Michael (FNIH) [T] [b6]
Shen, Yuan Li (FDA/CDER) [b6]
Stein, Peter (FDA/CDER) [b6]
Higgs, Elizabeth [b6]
Koroshetz, Walter [b6]
Farley, John [b6]
[b6]
Qashu, Felicia [b6]
Burgess, Timothy [b6]

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, May 13, 2020 10:04 PM
To: Melencio, Cheryl (FNIH) [T] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: JAMA Viewpoint on ACTIV: please review

Please help, tx

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 6:37 PM
To: Myles, Renate (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: JAMA Viewpoint on ACTIV: please review

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Subject: RE: JAMA Viewpoint on ACTIV: please review

No surprise there. We need to get permission from the EC/WG members quickly. What's the best way to do this?

Renate Myles, MBA
Deputy Director for Public Affairs
Office of Communications and Public Liaison
National Institutes of Health
Tel: [b6]

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Subject: FW: JAMA Viewpoint on ACTIV: please review

Hey Ashley and Rebecca,

Can you give these galley proofs a very close read, and let me know if you find anything amiss?

Renate, note that they are asking for the ACTIV website URL. Very timely, I'd say!

Francis

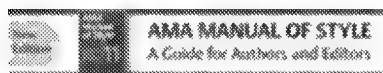
From: Stacy Christiansen [b6]
Sent: Wednesday, May 13, 2020 5:22 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Howard Bauchner [b6]; Karen Bucher [b6]
Subject: JAMA Viewpoint on ACTIV: please review

Dear Dr Collins,
Attached please find a proof of your Viewpoint for JAMA on the ACTIV initiative. We have typeset your figure herein, and I am cc'ing the illustrator, Karen Bucher, so we can handle any text or graphics changes simultaneously.

The only query to you is the completion of reference 5, the ACTIV portal URL.

I recognize how busy you must be, but I hope you can find time to review this proof so we can publish it quickly.
Thank you so much!
Best, Stacy

Stacy L. Christiansen, MA
Managing Editor, *JAMA*
Chair, *AMA Manual of Style*



Sent: 5/14/2020 10:24:05 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: RE: List -- just copy and paste in bcc. lists of April 3 plus working groups
Attachments: Master list for ACTIV 041520.xlsx

The following emails were missing from the list that went out. Cheryl -- attached is a revised master list (114 contacts) with names and emails which includes everyone.

Disbrow, Gary (OS/ASPR/BARDA) [b6]
Kim, Elizabeth <elkim@deloitte.com>;
Marston, Hilary (NIH/NIAID) [E] [b6]
Paul, Steve [b6]
Payne, David [b6]
Plump, Andy [b6]
Santos, Nancy [b6]
Shen, Yuan Li (FDA/CDER) [b6]

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, April 15, 2020 11:39 AM
To: Melencio, Cheryl (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: List -- just copy and paste in bcc. lists of April 3 plus working groups

I already sent the other list, given the time sensitivity. What has been added here that wasn't in the other one?

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Wednesday, April 15, 2020 11:19 AM
To: Parker, Ashley (NIH/OD) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6]
Subject: List -- just copy and paste in bcc. lists of April 3 plus working groups

Austin, Christopher (NIH/NCATS) [E] [b6]; Bright, Rick [b6]; Collins, Francis (NIH/OD) [E] [b6]; Corey, Larry [b6]; Disbrow, Gary (OS/ASPR/BARDA) [b6]; Dolsten, Mikael [b6]; Erbelding, Emily (NIH/NIAID) [E] [b6]; Fauci, Anthony (NIH/NIAID) [E] [b6]; Frankowski, David [b6]; Hudson, Thomas [b6]; James, Stephanie (FNIH) [T] [b6]; Klock, Kevin (FNIH) [T] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Marks, Peter (FDA/CBER) [b6]; Marston, Hilary (NIH/NIAID) [E] [b6]; Mascola, John [b6]; Meeker, David [b6]; Menetski, Joseph (FNIH) [T] [b6]; Pangalos, Mene [b6]; Pao, William [b6]; Paul, Steve [b6]; Perlmutter, Roger [b6]; Plump, Andy [b6]; Rasi, Guido [b6]; Reed, John [b6]; Rouse,

Doris [b6]; Santos, Michael (FNIH) [T] [b6] Skovronsky, Daniel
 [b6] Stein, Peter (FDA/CDER) [b6] Stoffels, Paul
 [b6]; Tabak, Lawrence (NIH/OD) [E] [b6] Tsai, John
 [b6]; Vessey, Rupert [b6] Virgin, Skip [b6] Wholley, David
 (FNIH) [T] [b6]; Woodcock, Janet (FDA/CDER) [b6] Young, John
 [b6] Adam, Stacey (FNIH) [T] [b6] Bascles, Lionel
 [b6] Cohen, Myron [b6] Corey, Larry [b6]
 Desrosiers, Betsy [b6] Dickens, Jim (NIH/NCATS) [C] [b6];
 Doroshov, James (NIH/NCI) [E] [b6] Goff, David (NIH/NHLBI) [E] [b6] Heaton,
 Penny [b6] King, James [b6] Kurilla, Mike [b6] Nayak,
 Seema (NIH/NIAID) [E] [b6] Parker, Ashley (NIH/OD) [E] [b6]; Payton, Manzine
 [b6]; Resnansky, Laura [b6] Srinivasan, Badhri
 [b6] Stein, Peter (FDA/CDER) [b6] Tountas, Karen (FNIH) [T]
 [b6] Vincent, Mike [b6] Wachtel, Jonathan <jwachtel@deloitte.com>;
 Woodcock, Janet (FDA/CDER) [b6] Adam, Stacey (FNIH) [T] [b6] Bozzette,
 Sam (NIH/NCATS) [E] [b6] Buchman, Tim (OS/ASPR/BARDA) (CTR) [b6]
 Butterson, Joan [b6] De Claro, R. Angelo (FDA/CDER) [b6]
 Draghia-Akli, Ruxandra [b6] Eisner, Mark [b6] Gottesdiener, Keith
 [b6] Hughes, Eric [b6] Judy Currier
 [b6] Kim, Elizabeth [b6] LaVange, Lisa [b6] Levy, Elliot
 [b6] Mellors, John [b6] Menon, Sandeep [b6] Parker,
 Ashley (NIH/OD) [E] [b6] Patel, Naimish [b6] Peppercorn, Amanda
 [b6] Poole, Mike [b6] Proschan, Michael
 [b6] Read, Sarah [b6] Santos, Michael (FNIH) [T] [b6]; Shen,
 Yuan Li (FDA/CDER) [b6] Stein, Peter (FDA/CDER) [b6] Adams, Peter
 (OS/ASPR/BARDA) [b6] Alvarez, Rosa <rosalvarez@deloitte.com>; Anderson, Annaliesa
 [b6] Baric, Ralph [b6] Carter, Kara [b6]
 Colvis, Christine [b6] Deming, Damon (FDA/CDER) [b6] Diamond,
 Michael [b6] Duncan, Ken [b6] Fernandes, Prabhavathi
 [b6] Gatto, Greg [b6] Grobler, Jay [b6] Hewitt, Judith
 [b6]; Jonson, Samantha (NIH/NCATS) [E] [b6] Lutz, Cat [b6]
 Menetski, Joseph (FNIH) [T] [b6] Nestle, Frank [b6] Ottinger, Liz
 [b6] Parker, Ashley (NIH/OD) [E] [b6] Payne, David
 Rappaport, Jay [b6] Stegmeier, Frank [b6]
 Young, John [b6] Annunziato, Paula [b6]; Arvin, Ann
 [b6] Buchbinder, Susan [b6] Corey, Larry [b6]
 Davis, Mark [b6] Emini, Emilio [b6] Hanon, Emmanuel
 [b6] Haynes, Barton [b6] Hotez, Peter [b6] Jansen,
 Kathrin [b6] Lanzavecchia, Antonio [b6] Lowy, Douglas (NIH/NCI) [E]
 [b6] Marks, Peter (FDA/CDER) [b6] Mascola, John (NIH/VRC) [E]
 [b6] Messonnier, Nancy (CDC/DDID/NCIRD/OD) [b6] Offit, Paul
 Parker, Ashley (NIH/OD) [E] [b6] Santos, Nancy [b6]
 Schuitemaker, Hanneke [b6] Tartaglia, Jim [b6] Tolman, Brett
 [b6]

Cheryl Melencio

Administrative Manager, Research Partnerships

Foundation for the National Institutes of Health

[b6]

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Stay at the forefront of FNIH news: fnih.org/newsletter

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/14/2020 1:14:07 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: Re: JAMA Viewpoint on ACTIV: please review

Hi Cheryl,

I'm on a ICD call with Francis, can you please send him the list of emails?

Thanks!
Ashley

On May 14, 2020, at 9:10 AM, Melencio, Cheryl (FNIH) [T] [b6] wrote:

Hi Ashley

I have added those who have been added to the working groups since Tuesday.

Cheryl

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

[b6]

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic

<image002.png>

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 10:10 PM
To: Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
Subject: RE: JAMA Viewpoint on ACTIV: please review

Here is what Cheryl provided as of Friday – she may have additional updates.

Vaccines:

Annunziato, Paula [b6]
Arvin, Ann [b6]
Buchbinder, Susan [b6]
Corey, Larry [b6]
Davis, Mark <[b6]>

Emini, Emilio [b6]
Hanon, Emmanuel [b6]
Haynes, Barton [b6]
Hotez, Peter [b6]
Jansen, Kathrin [b6]
Lanzavecchia, Antonio [b6]
Lowy, Douglas (NIH/NCI) [E] [b6]
Marks, Peter (FDA/CBER) [b6]
Mascola, John [b6]
Messonnier, Nancy (CDC/DDID/NCIRD/OD) [b6]
Offit, Paul [b6]
Parker, Ashley (NIH/OD) [E] [b6]
Santos, Michael (FNIH) [b6]
Santos, Nancy [b6]
Schuitemaker, Hanneke [b6]
Tartaglia, Jim [b6]
Tolman, Brett btolman@deloitte.com;
Zaks, Tal [b6]
Qashu, Felicia [b6]
Michael, Nelson, [b6]

Clinical Capacity

Adam, Stacey (FNIH) [T] [b6]
Bascles, Lionel [b6]
Cohen, Myron [b6]
Corey, Larry [b6]
Desrosiers, Betsy [b6]
Dickens, Jim (NIH/NCATS) [C] [b6]
Doroshov, James (NIH/NCI) [E] [b6]
Goff, David (NIH/NHLBI) [E] [b6]
Heaton, Penny [b6]
Kurilla, Mike [b6]
Nayak, Seema (NIH/NIAID) [E] [b6]
Parker, Ashley (NIH/OD) [E] [b6]
Payton, Manzine [b6]
Resnansky, Laura [b6]
Srinivasan, Badhri [b6]
Stein, Peter (FDA/CDER) [b6]
Tountas, Karen (FNIH) [T] [b6]
Vincent, Mike [b6]
Wachtel, Jonathan <jwachtel@deloitte.com>;
Woodcock, Janet (FDA/CDER) [b6]

[b6]

Qashu, Felicia [b6]
Weinmann, Gail [b6]
Mensah, George [b6]

Preclinical

Adams, Peter (OS/ASPR/BARDA) [b6]
Alvarez, Rosa <rosalvarez@deloitte.com>;
Anderson, Annaliesa [b6]
Baric, Ralph [b6]
Carter, Kara [b6]
Colvis, Christine [b6]
Deming, Damon (FDA/CDER) [b6]
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Duncan, Ken [b6]
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Gatto, Greg [b6]
Grobler, Jay [b6]
Hewitt, Judith [b6]
Jonson, Samantha (NIH/NCATS) [E]
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Rao, Srinivas [b6]
Rappaport, Jay [b6]
Stegmeier, Frank [b6]
Young, John [b6]
Qashu, Felicia [b6]
Pitt, Louise [b6]
Cihlar, Tomas [b6]
Fessel, Josh [b6]
Punturieri, Tony [b6]
Charette, Marc [b6]

Tx Clinical

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Currier, Judy [b6]
De Claro, R. Angelo (FDA/CDER) [b6]
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Eisner, Mark [b6]
Garner, Carlos [b6]
Gottesdiener, Keith [b6]
Hughes, Eric [b6]
Kim, Elizabeth <elkim@deloitte.com>;
LaVange, Lisa [b6]
Levy, Elliot [b6]

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Menon, Sandeep [b6]
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Cc: Howard Bauchner [b6]; Karen Bucher
[b6]
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Stacy L. Christiansen, MA
Managing Editor, JAMA
Chair, AMA Manual of Style

<image001.jpg>

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CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
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As requested by Ashley

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Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health
[b6]
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



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Schuitemaker, Hanneke [b6]
Tartaglia, Jim [b6]
Tolman, Brett btolman@deloitte.com;
Zaks, Tal [b6]
Qashu, Felicia [b6]
Michael, Nelson [b6]

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Bascles, Lionel [b6]
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Desrosiers, Betsy [b6]
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Doroshov, James (NIH/NCI) [E] [b6]
Goff, David (NIH/NHLBI) [E] [b6]
Heaton, Penny [b6]
Kurilla, Mike [b6]
Nayak, Seema (NIH/NIAID) [E] [b6]
Parker, Ashley (NIH/OD) [E] [b6]
Payton, Manzine [b6]
Resnansky, Laura [b6]
Srinivasan, Badhri [b6]
Stein, Peter (FDA/CDER) [b6]
Tountas, Karen (FNIH) [T] [b6]
Vincent, Mike [b6]
Wachtel, Jonathan <jwachtel@deloitte.com>;
Woodcock, Janet (FDA/CDER) [b6]
[b6]
Qashu, Felicia [b6]
Weinmann, Gail [b6]
Mensah, George [b6]

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Adams, Peter (OS/ASPR/BARDA) [b6]
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Anderson, Annaliesa [b6]
Baric, Ralph [b6]
Carter, Kara [b6]
Colvis, Christine [b6]
Deming, Damon (FDA/CDER) [b6]
Diamond, Michael [b6]
Duncan, Ken [b6]
Fernandes, Prabhavathi [b6]
Gatto, Greg [b6]
Grobler, Jay [b6]
Hewitt, Judith [b6]
Jonson, Samantha (NIH/NCATS) [E]
[b6]
Lutz, Cat [b6]
Menetski, Joseph (FNIH) [T] [b6]
Nestle, Frank [b6]
Ottinger, Liz [b6]
Parker, Ashley (NIH/OD) [E] [b6]
Payne, David [b6]
Rao, Srinivas< [b6]
Rappaport, Jay [b6]
Stegmeier, Frank< [b6]
Young, John [b6]
Qashu, Felicia< [b6]
[b6]
Cihlar, Tomas [b6]
Fessel, Josh< [b6]
Punturieri, Tony< [b6]
Charette, Marc< [b6]

Tx Clinical

Adam, Stacey (FNIH) [T] [b6]
Bozzette, Sam (NIH/NCATS) [E] [b6]
Buchman, Tim (OS/ASPR/BARDA) (CTR) [b6]
Butterton, Joan [b6]
Currier, Judy [b6]
De Claro, R. Angelo (FDA/CDER) [b6]
Draghia-Akli, Ruxandra [b6]
Eisner, Mark [b6]
Garner, Carlos< [b6]
Gottesdiener, Keith [b6]
Hughes, Eric [b6]
Kim, Elizabeth [b6]

LaVange, Lisa [b6]
Levy, Elliot [b6]
Mellors, John [b6]
Menon, Sandeep [b6]
Parker, Ashley (NIH/OD) [E] [b6]
Patel, Naimish [b6]
Peppercorn, Amanda [b6]
Poole, Mike [b6]
Proschan, Michael [b6]
Read, Sarah [b6]
Santos, Michael (FNIH) [T] [b6]
Shen, Yuan Li (FDA/CDER) [b6]
Stein, Peter (FDA/CDER) < [b6]
Higgs, Elizabeth [b6]
Koroshetz, Walter [b6]
Farley, John [b6]
[b6]
Qashu, Felicia [b6]
Burgess, Timothy [b6]
Reineck, Lora [b6]
Aggarwal, Neil [b6]

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, May 13, 2020 10:04 PM
To: Melencio, Cheryl (FNIH) [T] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: JAMA Viewpoint on ACTIV: please review

Please help, tx

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 6:37 PM
To: Myles, Renate (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: JAMA Viewpoint on ACTIV: please review

I'm glad to send the query if someone will draft the message and someone else (Cheryl?) will send me the list of e-mails for all of the WG members.

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Sent: Wednesday, May 13, 2020 6:12 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]

Wholley, David (FNIH) [T] [b6]
Subject: RE: JAMA Viewpoint on ACTIV: please review

No surprise there. We need to get permission from the EC/WG members quickly. What's the best way to do this?

Renate Myles, MBA
Deputy Director for Public Affairs
Office of Communications and Public Liaison
National Institutes of Health
Tel: [b6]

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 5:48 PM
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Cc: Myles, Renate (NIH/OD) [E] [b6]; Burklow, John (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: FW: JAMA Viewpoint on ACTIV: please review

Hey Ashley and Rebecca,

Can you give these galley proofs a very close read, and let me know if you find anything amiss?

Renate, note that they are asking for the ACTIV website URL. Very timely, I'd say!

Francis

From: Stacy Christiansen [b6]
Sent: Wednesday, May 13, 2020 5:22 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Howard Bauchner [b6]; Karen Bucher [b6]
Subject: JAMA Viewpoint on ACTIV: please review

Dear Dr Collins,
Attached please find a proof of your Viewpoint for JAMA on the ACTIV initiative. We have typeset your figure herein, and I am cc'ing the illustrator, Karen Bucher, so we can handle any text or graphics changes simultaneously.

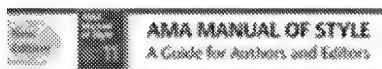
The only query to you is the completion of reference 5, the ACTIV portal URL.

I recognize how busy you must be, but I hope you can find time to review this proof so we can publish it quickly.

Thank you so much!

Best, Stacy

Stacy L. Christiansen, MA
Managing Editor, JAMA
Chair, AMA Manual of Style



Sent: 5/14/2020 2:00:14 PM
Subject: ACTION: Making your ACTIV Participation Public

Hi Francis,

I've pasted a slightly revised draft email OCPL provided to ask the ACTIV EC and WG members permission to list their names on the website. Renate – there are a few new members working group members, we can work together to update the list.

To:

Cc: Myles, Renate (NIH/OD) [E] [b6] Meltzer, Abbey (FNIH) [T] [b6] Wholley, David (FNIH) [T] [b6]

Bcc: Stoffels, Paul [b6] Fauci, Anthony (NIH/NIAID) [E]

[b6] Gibbons, Gary (NIH/NHLBI) [E] [b6]; Pao, William
[b6]; Woodcock, Janet (FDA/CDER) [b6]; Annunziato, Paula

[b6] Arvin, Ann [b6] Buchbinder, Susan
[b6] Corey, Larry [b6] Davis, Mark [b6] Emini,

Emilio [b6]; Hanon, Emmanuel [b6]; Haynes, Barton

[b6] Hotez, Peter [b6] Jansen, Kathrin [b6]
Lanzavecchia, Antonio [b6] Lowy, Douglas (NIH/NCI) [E] [b6] Marks, Peter

(FDA/CBER) [b6] Mascola, John [b6]; Messonnier, Nancy
(CDC/DDID/NCIRD/OD) [b6] Offit, Paul [b6] Parker, Ashley (NIH/OD) [E]

[b6]; Santos, Michael (FNIH) [T] [b6] Santos, Nancy [b6]

Schuitemaker, Hanneke [b6] Tartaglia, Jim [b6]; Tolman, Brett

<btolman@deloitte.com>; Zaks, Tal [b6] Qashu, Felicia (NIH/OD) [E] [b6]

Michael, Nelson, [b6]; Adam, Stacey (FNIH) [T] [b6]; Bascles, Lionel

[b6] Cohen, Myron [b6] Corey, Larry [b6];

Desrosiers, Betsy [b6] Dickens, Jim (NIH/NCATS) [C] [b6];

Doroshov, James (NIH/NCI) [E] [b6] Goff, David (NIH/NHLBI) [E] [b6]; Heaton,

Penny [b6]; Kurilla, Mike [b6] Nayak, Seema (NIH/NIAID) [E]

[b6] Parker, Ashley (NIH/OD) [E] [b6]; Payton, Manzine

[b6] Resnansky, Laura [b6] Srinivasan, Badhri

[b6]; Stein, Peter (FDA/CDER) [b6]ountas, Karen (FNIH) [T]

[b6] Vincent, Mike [b6]; Wachtel, Jonathan <jwachtel@deloitte.com>;

Woodcock, Janet (FDA/CDER) [b6] Sizemore, Christine

(NIH/FIC) [E] [b6] Victoria Davey [b6]; Qashu, Felicia (NIH/OD) [E]

[b6]; Weinmann, [b6]; Mensah, [b6]

Adam, Stacey (FNIH) [T] [b6] Bozzette, Sam (NIH/NCATS) [E] [b6]; Buchman, Tim

(OS/ASPR/BARDA) (CTR) [b6] Butterton, Joan [b6] Currier, Judy

[b6] De Claro, R. Angelo (FDA/CDER) [b6] Draghia-Akli, Ruxandra

[b6]; Eisner, Mark [b6]; Garner,

Carlos [b6] Gottesdiener, Keith [b6]; Hughes, Eric

[b6] Kim, Elizabeth <elkim@deloitte.com>; LaVange, Lisa [b6] Levy, Elliot

[b6] Mellors, John [b6]; Menon, Sandeep [b6]; Parker,

Ashley (NIH/OD) [E] [b6] Patel, Naimish [b6]; Peppercorn, Amanda

[b6] Poole, Mike [b6] Proschan, Michael

[b6] Read, Sarah [b6] Santos, Michael (FNIH) [T] [b6] Shen,

Yuan Li (FDA/CDER) [b6] Stein, Peter (FDA/CDER) [b6] Higgs, Elizabeth

[b6] Koroshetz, Walter [b6] Farley, John [b6]

[b6] Qashu, Felicia [b6] Burgess,

Timothy [b6] Reineck, Lora [b6] Aggarwal, Neil [b6]

APAR0000017200

Subject: ACTION: Making your ACTIV Participation Public

Dear Colleagues:

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer and David Wholley by 3:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed as part of the ACTIV membership.**

Thanks,
Francis

Francis Collins, MD, PhD
NIH Director

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/14/2020 2:05:10 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: RE: JAMA Viewpoint on ACTIV: please review

That's fine – thanks! I am packaging the email to make it easy for Francis to send.

Ashley

From: Wholley, David (FNIH) [T] [b6]
Sent: Thursday, May 14, 2020 9:32 AM
To: Parker, Ashley (NIH/OD) [E] [b6] Melencio, Cheryl (FNIH) [T] [b6]
Subject: RE: JAMA Viewpoint on ACTIV: please review

I think I just forwarded Cheryl's email to you on to Francis. Is that what you wanted?

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 9:14 AM
To: Melencio, Cheryl (FNIH) [T] [b6]
Cc: Wholley, David (FNIH) [T] [b6]
Subject: Re: JAMA Viewpoint on ACTIV: please review

Hi Cheryl,

I'm on a ICD call with Francis, can you please send him the list of emails?

Thanks!
Ashley

On May 14, 2020, at 9:10 AM, Melencio, Cheryl (FNIH) [T] [b6] wrote:

Hi Ashley

I have added those who have been added to the working groups since Tuesday.

Cheryl

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health
[b6]

fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic

<image002.png>

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 10:10 PM
To: Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
Subject: RE: JAMA Viewpoint on ACTIV: please review

Here is what Cheryl provided as of Friday – she may have additional updates.

Vaccines:

Annunziato, Paula [b6]
Arvin, Ann [b6]
Buchbinder, Susan [b6]
Corey, Larry <[b6]>
Davis, Mark <[b6]>
Emini, Emilio [b6]
Hanon, Emmanuel [b6]
Haynes, Barton [b6]
Hotez, Peter [b6]
Jansen, Kathrin [b6]
Lanzavecchia, Antonio <[b6]>
Lowy, Douglas (NIH/NCI) [E] [b6]
Marks, Peter (FDA/CBER) [b6]
Mascola, John [b6]
Messonnier, Nancy (CDC/DDID/NCIRD/OD) [b6]
Offit, Paul [b6]
Parker, Ashley (NIH/OD) [E] [b6]
Santos, Michael (FNIH) [b6]
Santos, Nancy [b6]
Schuitemaker, Hanneke [b6]
Tartaglia, Jim [b6]
Tolman, Brett btolman@deloitte.com;
Zaks, Tal <[b6]>
Qashu, Felicia <[b6]>
Michael, Nelson, [b6]

Clinical Capacity

Adam, Stacey (FNIH) [T] [b6]
Bascles, Lionel [b6]
Cohen, Myron [b6]
Corey, Larry [b6]
Desrosiers, Betsy <elizabeth [b6]>
Dickens, Jim (NIH/NCATS) [C] [b6]
Doroshov, James (NIH/NCI) [E] [b6]
Goff, David (NIH/NHLBI) [E] [b6]
Heaton, Penny [b6]
Kurilla, Mike [b6]
Nayak, Seema (NIH/NIAID) [E] [b6]
Parker, Ashley (NIH/OD) [E] [b6]
Payton, Manzine [b6]

Resnansky, Laura [b6]
Srinivasan, Badhri [b6]
Stein, Peter (FDA/CDER) <[b6]>
Tountas, Karen (FNIH) [T]
Vincent, Mike <[b6]>
Wachtel, Jonathan <jwachtel@deloitte.com>
Woodcock, Janet (FDA/CDER) [b6]
[b6]
Qashu, Felicia <[b6]>
Weinmann, Gail [b6]
Mensah, George [b6]

Preclinical

Adams, Peter (OS/ASPR/BARDA) <[b6]>
Alvarez, Rosa <rosalvarez@deloitte.com>
Anderson, Annaliesa [b6]
Baric, Ralph [b6]
Carter, Kara [b6]
Colvis, Christine [b6]
Deming, Damon (FDA/CDER) <[b6]>
Diamond, Michael [b6]
Duncan, Ken [b6]
Fernandes, Prabhavathi [b6]
Gatto, Greg [b6]
Grobler, Jay [b6]
Hewitt, Judith [b6]
Jonson, Samantha (NIH/NCATS) [E]
[b6]
Lutz, Cat [b6]
Menetski, Joseph (FNIH) [T] [b6]
Nestle, Frank [b6]
Ottinger, Liz [b6]
Parker, Ashley (NIH/OD) [E] [b6]
Payne, David [b6]
Rao, Srinivas [b6]
Rappaport, Jay [b6]
Stegmeier, Frank [b6]
Young, John [b6]
Qashu, Felicia [b6]
Pitt, Louise <[b6]>
Cihlar, Tomas [b6]
Fessel, Josh [b6]
Punturieri, Tony [b6]
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Currier, Judy [b6]
De Claro, R. Angelo (FDA/CDER) [b6]
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Garner, Carlos [b6]
Gottesdiener, Keith [b6]
Hughes, Eric <[b6]>
Kim, Elizabeth <elkim@deloitte.com>;
LaVange, Lisa [b6]
Levy, Elliot [b6]
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Cc: Parker, Ashley (NIH/OD) [E]
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Please help, tx

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Sent: Wednesday, May 13, 2020 6:37 PM
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Cc: Burklow, John (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E]
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[b6]; Wholley, David (FNIH) [T] [b6]
Subject: RE: JAMA Viewpoint on ACTIV: please review

No surprise there. We need to get permission from the EC/WG members quickly. What's the best way to do this?

Renate Myles, MBA
Deputy Director for Public Affairs
Office of Communications and Public Liaison
National Institutes of Health
Tel: [b6]

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Sent: Wednesday, May 13, 2020 5:48 PM
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[b6]
Cc: Myles, Renate (NIH/OD) [E] [b6]; Burklow, John (NIH/OD) [E]
[b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David
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Subject: FW: JAMA Viewpoint on ACTIV: please review

Hey Ashley and Rebecca,

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Renate, note that they are asking for the ACTIV website URL. Very timely, I'd say!

Francis

From: Stacy Christiansen [b6]
Sent: Wednesday, May 13, 2020 5:22 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Howard Bauchner [b6]; Karen Bucher
[b6]
Subject: JAMA Viewpoint on ACTIV: please review

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The only query to you is the completion of reference 5, the ACTIV portal URL.

I recognize how busy you must be, but I hope you can find time to review this proof so we can publish it quickly.

Thank you so much!

Best, Stacy

Stacy L. Christiansen, MA

Managing Editor, *JAMA*

Chair, *AMA Manual of Style*

<image001.jpg>

Sent: 5/14/2020 2:10:12 PM
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CC: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: RE: JAMA Viewpoint on ACTIV: please review

Thanks, David. Francis – I am connecting with Renate to get an updated time on the request to have the responses back from the ACTIV EC and WG members. I will package the draft message along with the emails to make it easy for you to send.

From: Wholley, David (FNIH) [T] [b6]
Sent: Thursday, May 14, 2020 9:29 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
Subject: FW: JAMA Viewpoint on ACTIV: please review

As requested by Ashley

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Thursday, May 14, 2020 9:10 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Wholley, David (FNIH) [T] [b6]
Subject: RE: JAMA Viewpoint on ACTIV: please review

Hi Ashley

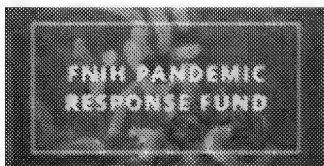
I have added those who have been added to the working groups since Tuesday.

Cheryl

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

[b6]
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 10:10 PM
To: Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
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Hanon, Emmanuel [b6]
Haynes, Barton [b6]
Hotez, Peter [b6]
Jansen, Kathrin [b6]
Lanzavecchia, Antonio [b6]
Lowy, Douglas (NIH/NCI) [E] [b6]
Marks, Peter (FDA/CBER) [b6]
Mascola, John [b6]
Messonnier, Nancy (CDC/DDID/NCIRD/OD) [b6]
Offit, Paul [b6]
Parker, Ashley (NIH/OD) [E] [b6]
Santos, Michael (FNIH) [b6]
Santos, Nancy [b6]
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Tartaglia, Jim [b6]
Tolman, Brett btolman@deloitte.com
Zaks, Tal [b6]
Qashu, Felicia [b6]
Michael, Nelson, [b6]

Clinical Capacity

Adam, Stacey (FNIH) [T] [b6]
Bascles, Lionel [b6]
Cohen, Myron [b6]
Corey, Larry [b6]
Desrosiers, Betsy [b6]
Dickens, Jim (NIH/NCATS) [C] [b6]
Doroshov, James (NIH/NCI) [E] [b6]
Goff, David (NIH/NHLBI) [E] [b6]
Heaton, Penny [b6]
Kurilla, Mike [b6]
Nayak, Seema (NIH/NIAID) [E] [b6]
Parker, Ashley (NIH/OD) [E] [b6]
Payton, Manzine < [b6]
Resnansky, Laura < [b6]
Srinivasan, Badhri [b6]

Stein, Peter (FDA/CDER) [b6]
Tountas, Karen (FNIH) [T] [b6]
Vincent, Mike [b6]
Wachtel, Jonathan <jwachtel@deloitte.com>;
Woodcock, Janet (FDA/CDER) [b6]
[b6]
Qashu, Felicia [b6];
Weinmann, Gail [b6]
Mensah, George [b6]

Preclinical

Adams, Peter (OS/ASPR/BARDA) [b6]
Alvarez, Rosa <rosalvarez@deloitte.com>;
Anderson, Annaliesa [b6]
Baric, Ralph [b6]
Carter, Kara [b6]
Colvis, Christine [b6]
Deming, Damon (FDA/CDER) [b6]
Diamond, Michael [b6];
Duncan, Ken [b6]
Fernandes, Prabhavathi [b6]
Gatto, Greg [b6]
Grobler, Jay [b6]
Hewitt, Judith [b6];
Jonson, Samantha (NIH/NCATS) [E]
[b6];
Lutz, Cat [b6]
Menetski, Joseph (FNIH) [T] [b6]
Nestle, Frank [b6]
Ottinger, Liz [b6]
Parker, Ashley (NIH/OD) [E] [b6]
Payne, David [b6]
Rao, Srinivas [b6]
Rappaport, Jay [b6]
Stegmeier, Frank [b6]
Young, John [b6]
Qashu, Felicia [b6];
[b6];
Cihlar, Tomas [b6]
Fessel, Josh [b6]
Punturieri, Tony [b6];
Charette, Marc [b6]

Tx Clinical

Adam, Stacey (FNIH) [T] [b6]

Bozzette, Sam (NIH/NCATS) [E] [b6]
Buchman, Tim (OS/ASPR/BARDA) (CTR) [b6]
Butterton, Joan [b6]
Currier, Judy [b6]
De Claro, R. Angelo (FDA/CDER) [b6]
Draghia-Akli, Ruxandra [b6]
Eisner, Mark [b6]
Garner, Carlos [b6]
Gottesdiener, Keith [b6]
Hughes, Eric <[b6]>
Kim, Elizabeth <elkim@deloitte.com>;
LaVange, Lisa [b6]
Levy, Elliot [b6]
Mellors, John [b6]
Menon, Sandeep [b6]
Parker, Ashley (NIH/OD) [E] [b6]
Patel, Naimish [b6]
Peppercorn, Amanda [b6]
Poole, Mike [b6]
Proschan, Michael [b6]
Read, Sarah [b6]
Santos, Michael (FNIH) [T] [b6]
Shen, Yuan Li (FDA/CDER) [b6]
Stein, Peter (FDA/CDER) [b6]
Higgs, Elizabeth [b6];
Koroshetz, Walter [b6]
Farley, John <[b6]>
[b6]
Qashu, Felicia [b6]
Burgess, Timothy <[b6]>
Reineck, Lora <[b6]>
Aggarwal, Neil [b6]

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, May 13, 2020 10:04 PM
To: Melencio, Cheryl (FNIH) [T] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: JAMA Viewpoint on ACTIV: please review

Please help, tx

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 6:37 PM
To: Myles, Renate (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Parker, Ashley

(NIH/OD) [E] [b6]

Subject: RE: JAMA Viewpoint on ACTIV: please review

I'm glad to send the query if someone will draft the message and someone else (Cheryl?) will send me the list of e-mails for all of the WG members.

From: Myles, Renate (NIH/OD) [E] [b6]

Sent: Wednesday, May 13, 2020 6:12 PM

To: Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]

Subject: RE: JAMA Viewpoint on ACTIV: please review

No surprise there. We need to get permission from the EC/WG members quickly. What's the best way to do this?

Renate Myles, MBA

Deputy Director for Public Affairs

Office of Communications and Public Liaison

National Institutes of Health

Tel: [b6]

From: Collins, Francis (NIH/OD) [E] [b6]

Sent: Wednesday, May 13, 2020 5:48 PM

To: Parker, Ashley (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]

Cc: Myles, Renate (NIH/OD) [E] [b6]; Burklow, John (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]

Subject: FW: JAMA Viewpoint on ACTIV: please review

Hey Ashley and Rebecca,

Can you give these galley proofs a very close read, and let me know if you find anything amiss?

Renate, note that they are asking for the ACTIV website URL. Very timely, I'd say!

Francis

From: Stacy Christiansen [b6]

Sent: Wednesday, May 13, 2020 5:22 PM

To: Collins, Francis (NIH/OD) [E] [b6]

Cc: Howard Bauchner [b6]; Karen Bucher [b6]

Subject: JAMA Viewpoint on ACTIV: please review

Dear Dr Collins,

Attached please find a proof of your Viewpoint for JAMA on the ACTIV initiative. We have typeset your figure herein, and I am cc'ing the illustrator, Karen Bucher, so we can handle any text or graphics changes simultaneously.

The only query to you is the completion of reference 5, the ACTIV portal URL.

I recognize how busy you must be, but I hope you can find time to review this proof so we can publish it quickly.

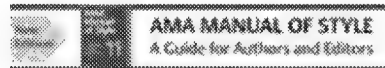
Thank you so much!

Best, Stacy

Stacy L. Christiansen, MA

Managing Editor, *JAMA*

Chair, *AMA Manual of Style*



From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/14/2020 2:32:15 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: RE: JAMA Viewpoint on ACTIV: please review

Thanks. I am looping in Abbey so that she will be aware the an email will go out with her name on the cc line. That was my purpose for cc'ing Abbey.

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Thursday, May 14, 2020 10:29 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: JAMA Viewpoint on ACTIV: please review

Ashley

I sent the updated working group member list to Abbey Meltzer a little while ago.

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health
[b6]
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 10:20 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Myles, Renate (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Meltzer, Abbey (FNIH) [T] [b6]
Subject: RE: JAMA Viewpoint on ACTIV: please review

To be clear the new WG members are on this email thread below but we will need to add them to draft webpage once we have permission to list their names.

+ Abbey.

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]

Sent: Thursday, May 14, 2020 10:16 AM

To: Collins, Francis (NIH/OD) [E] [b6]; Myles, Renate (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]

Subject: RE: JAMA Viewpoint on ACTIV: please review

Hi Francis,

David forwarded the emails this morning. Please see below to make it easy to send.

I've pasted a slightly revised draft email OCPL provided (to also cc Renate, Abbey and David?). Renate – there are a few new members working group members, we can work together to update the list.

To:

Cc: Myles, Renate (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]

Bcc: Stoffels, Paul [b6]; Fauci, Anthony (NIH/NIAID) [E]

[b6]; Gibbons, Gary (NIH/NHLBI) [E] [b6]; Pao, William [b6]; Woodcock, Janet (FDA/CDER) [b6]; Annunziato, Paula

[b6]; Arvin, Ann [b6]; Buchbinder, Susan [b6]; Corey, Larry [b6]; Davis, Mark [b6]; Emini, Emilio [b6]; Hanon, Emmanuel [b6]; Haynes, Barton [b6]; Hotez, Peter [b6]; Jansen, Kathrin [b6]; Lanzavecchia, Antonio [b6]; Lowy, Douglas (NIH/NCI) [E] [b6]; Marks, Peter (FDA/CBER) [b6]; Mascola, John [b6]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [b6]; Offit, Paul [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Santos, Michael (FNIH) [T] [b6]; Santos, Nancy [b6]

Schuitemaker, Hanneke [b6]; Tartaglia, Jim [b6]; Tolman, Brett [b6]; <btolman@deloitte.com>; Zaks, Tal [b6]; Qashu, Felicia (NIH/OD) [E] [b6]; Michael, Nelson, [b6]; Adam, Stacey (FNIH) [T] [b6]; Bascles, Lionel [b6]; Cohen, Myron [b6]; Corey, Larry [b6]; Desrosiers, Betsy [b6]; Dickens, Jim (NIH/NCATS) [C] [b6]; Doroshov, James (NIH/NCI) [E] [b6]; Goff, David (NIH/NHLBI) [E] [b6]; Heaton, Penny [b6]; Kurilla, Mike [b6]; Nayak, Seema (NIH/NIAID) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Payton, Manzine [b6]; Resnansky, Laura [b6]; Srinivasan, Badhri [b6]; Stein, Peter (FDA/CDER) [b6]; Karen (FNIH) [T] [b6]; Vincent, Mike [b6]; Wachtel, Jonathan [b6]; Woodcock, Janet (FDA/CDER) [b6]; Sizemore, Christine (NIH/FIC) [E] [b6]; Victoria Davey [b6]; Qashu, Felicia (NIH/OD) [E] [b6]; Weinmann, [b6]; Mensah, [b6]; Adam, Stacey (FNIH) [T] [b6]; Bozette, Sam (NIH/NCATS) [E] [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [b6]; Butterton, Joan [b6]; Currier, Judy [b6]; De Claro, R. Angelo (FDA/CDER) [b6]; Draghia-Akli, Ruxandra [b6]; Eisner, Mark [b6]; Garner, Carlos [b6]; Gottesdie [b6]; Hughes, Eric [b6]; Kim, Elizabeth [b6]; LaVange, Lisa [b6]; Levy, Elliot [b6]; Mellors, John [b6]; Menon, Sandeep [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Patel, Naimish [b6]; Peppercorn, Amanda [b6]; Poole, Mike [b6]; Proschan, Michael [b6]; Read, Sarah [b6]; Santos, Michael (FNIH) [T] [b6]; Shen, [b6]

Yuan Li (FDA/CDER) [b6]; Stein, Peter (FDA/CDER) [b6]
[b6]; Koroshetz, Walter [b6]; Farley, John [b6];
[b6]; Qashu, Felicia [b6]; Burgess,
Timothy [b6]; Reineck, Lora [b6]; Aggarwal, Neil [b6]

Subject: ACTION: Making your ACTIV Participation Public

Dear Colleagues:

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed as part of the ACTIV membership.**

Thanks,
Francis

Francis Collins, MD, PhD
NIH Director

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/14/2020 2:35:53 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: RE: JAMA Viewpoint on ACTIV: please review

Yes, I've added them to my email highlighted below. I got some rest last night and I am on top of it – greatly appreciate it the cross checking! Team work! 😊

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Thursday, May 14, 2020 10:31 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: JAMA Viewpoint on ACTIV: please review

Here are the Executive Committee emails:

Collins, Francis (NIH/OD) [E] [b6]; Fauci, Anthony (NIH/NIAID) [E] [b6]; Gibbons, Gary (NIH/NHLBI) [E] [b6]; Stoffels, Paul [b6]; Pao, William [b6]; Dolsten, Mikael [b6]

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

[b6]
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 10:16 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Myles, Renate (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
Subject: RE: JAMA Viewpoint on ACTIV: please review

Hi Francis,

David forwarded the emails this morning. Please see below to make it easy to send.

I've pasted a slightly revised draft email OCPL provided (to also cc Renate, Abbey and David?). Renate – there are a few new members working group members, we can work together to update the list.

To:

Cc: Myles, Renate (NIH/OD) [E] [b6] Meltzer, Abbey (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]

Bcc: Stoffels, Paul [b6] Fauci, Anthony (NIH/NIAID) [E]

[b6] Gibbons, Gary (NIH/NHLBI) [E] [b6]; Pao, William [b6] Woodcock, Janet (FDA/CDER) [b6] Annunziato, Paula

[b6] Arvin, Ann [b6] Buchbinder, Susan [b6] Corey, Larry [b6] Davis, Mark [b6] Emini, Emilio [b6]; Hanon, Emmanuel [b6]; Haynes, Barton [b6]; Hotez, Peter [b6]; Jansen, Kathrin [b6];

Lanzavecchia, Antonio [b6]; Lowy, Douglas (NIH/NCI) [E] [b6] Marks, Peter (FDA/CBER) [b6] Mascola, John [b6]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [b6]; Offit, Paul [b6]; Parker, Ashley (NIH/OD) [E]

[b6]; Santos, Michael (FNIH) [T] [b6] Santos, Nancy [b6] Schuitemaker, Hanneke [b6]; Tartaglia, Jim [b6] Tolman, Brett

<btolman@deloitte.com>; Zaks, Tal [b6]; Qashu, Felicia (NIH/OD) [E] [b6] Michael, Nelson, [b6] Adam, Stacey (FNIH) [T] [b6]; Bascles, Lionel [b6]; Cohen, Myron [b6] Corey, Larry [b6]

Desrosiers, Betsy [b6]; Dickens, Jim (NIH/NCATS) [C] [b6]; Doroshov, James (NIH/NCI) [E] [b6]; Goff, David (NIH/NHLBI) [E] [b6]; Heaton, Penny [b6]; Kurilla, Mike [b6] Nayak, Seema (NIH/NIAID) [E]

[b6] Parker, Ashley (NIH/OD) [E] [b6]; Payton, Manzine [b6]; Resnansky, Laura [b6]; Srinivasan, Badhri [b6]; Stein, Peter (FDA/CDER) [b6] Tountas, Karen (FNIH) [T]

[b6]; Vincent, Mike [b6]; Wachtel, Jonathan <jwachtel@deloitte.com>; Woodcock, Janet (FDA/CDER) [b6]; Sizemore, Christine (NIH/FIC) [E] [b6]; Victoria Davey [b6]; Qashu, Felicia (NIH/OD) [E]

[b6]; Weinmann, [b6] Mensah, [b6] Adam, Stacey (FNIH) [T] [b6] Bozette, Sam (NIH/NCATS) [E] [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [b6]; Butterton, Joan [b6]; Currier, Judy [b6]; De Claro, R. Angelo (FDA/CDER) [b6] Draghia-Akli, Ruxandra [b6]; Eisner, Mark [b6] Garner, Carlos [b6] Gottesdiener, Keith [b6] Hughes, Eric [b6]; Kim, Elizabeth <elkim@deloitte.com>; LaVange, Lisa [b6] Levy, Elliot [b6]; Mellors, John [b6] Menon, Sandeep [b6] Parker, Ashley (NIH/OD) [E] [b6]; Patel, Naimish [b6]; Peppercorn, Amanda [b6] Poole, Mike [b6]; Proschan, Michael [b6]; Read, Sarah [b6] Santos, Michael (FNIH) [T] [b6] Shen, Yuan Li (FDA/CDER) [b6]; Stein, Peter (FDA/CDER) [b6] Higgs, Elizabeth [b6]; Koroshetz, Walter [b6] Farley, John [b6] [b6] Qashu, Felicia [b6]; Burgess, Timothy [b6] Reineck, Lora [b6] Aggarwal, Neil [b6]

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APAR0000013282-2444206

send your responses to me, cc'ing Renate Myles, Abbey Meltzer and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed as part of the ACTIV membership.

Thanks,
Francis

Francis Collins, MD, PhD
NIH Director

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/14/2020 2:37:48 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: JAMA Viewpoint on ACTIV: please review

Ok Great!

From: Wholley, David (FNIH) [T] [b6]
Sent: Thursday, May 14, 2020 10:37 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: JAMA Viewpoint on ACTIV: please review

yes

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 10:34 AM
To: Wholley, David (FNIH) [T] [b6]
Subject: RE: JAMA Viewpoint on ACTIV: please review

Has not gone out yet but I've placed everyone's email in the bcc line except for Renate, Abbey, and you. Figured FNIH would want to be looped in to those responses as well?

From: Wholley, David (FNIH) [T] [b6]
Sent: Thursday, May 14, 2020 10:29 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: JAMA Viewpoint on ACTIV: please review

This was sent as a .bcc yes?

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 10:16 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Myles, Renate (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
Subject: RE: JAMA Viewpoint on ACTIV: please review

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To:
Cc: Myles, Renate (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]

Bcc: Stoffels, Paul [b6] Fauci, Anthony (NIH/NIAID) [E]
 [b6] Gibbons, Gary (NIH/NHLBI) [E] [b6] Pao, William
 [b6] Woodcock, Janet (FDA/CDER) [b6] Annunziato, Paula
 [b6] Arvin, Ann [b6] Buchbinder, Susan
 [b6] Corey, Larry [b6] Davis, Mark [b6] Emini,
 Emilio [b6] Hanon, Emmanuel [b6] Haynes, Barton
 [b6] Hotez, Peter [b6] Jansen, Kathrin [b6]
 Lanzavecchia, Antonio [b6] Lowy, Douglas (NIH/NCI) [E] [b6] Marks, Peter
 (FDA/CBER) [b6] Mascola, John [b6] Messonnier, Nancy
 (CDC/DDID/NCIRD/OD) [b6] Offit, Paul [b6] Parker, Ashley (NIH/OD) [E]
 [b6] Santos, Michael (FNIH) [T] [b6] Santos, Nancy [b6]
 Schuitemaker, Hanneke [b6] Tartaglia, Jim [b6] Tolman, Brett
 <btolman@deloitte.com>; Zaks, Tal [b6] Qashu, Felicia (NIH/OD) [E] [b6]
 Michael, Nelson, [b6] Adam, Stacey (FNIH) [T] [b6] Bascles, Lionel
 [b6] Cohen, Myron [b6] Corey, Larry [b6]
 Desrosiers, Betsy [b6] Dickens, Jim (NIH/NCATS) [C] [b6]
 Doroshov, James (NIH/NCI) [E] [b6] Goff, David (NIH/NHLBI) [E] [b6] Heaton,
 Penny [b6] Kurilla, Mike [b6] Nayak, Seema (NIH/NIAID) [E]
 [b6] Parker, Ashley (NIH/OD) [E] [b6] Payton, Manzone
 [b6] Resnansky, Laura [b6] Srinivasan, Badhri
 [b6] Stein, Peter (FDA/CDER) [b6] Tountas, Karen (FNIH) [T]
 [b6] Vincent, Mike [b6] Wachtel, Jonathan <jwachtel@deloitte.com>;
 Woodcock, Janet (FDA/CDER) [b6] Sizemore, Christine
 (NIH/FIC) [E] [b6] Victoria Davey [b6] Qashu, Felicia (NIH/OD) [E]
 [b6] Weinmann, [b6] Mensah, [b6]
 Adam, Stacey (FNIH) [T] [b6] Bozzette, Sam (NIH/NCATS) [E] [b6] Buchman, Tim
 (OS/ASPR/BARDA) (CTR) [b6] Butters, Joan [b6] Currier, Judy
 [b6] De Claro, R. Angelo (FDA/CDER) [b6] Draghia-Akli, Ruxandra
 [b6] Eisner, Mark [b6] Garner,
 Carlos [b6] Gottesdiener, Keith [b6] Hughes, Eric
 [b6] Kim, Elizabeth <elkim@deloitte.com>; LaVange, Lisa [b6] Levy, Elliot
 [b6] Mellors, John [b6] Menon, Sandeep [b6] Parker,
 Ashley (NIH/OD) [E] [b6] Patel, Naimish [b6] Peppercorn, Amanda
 [b6] Poole, Mike [b6] Proschan, Michael
 [b6] Read, Sarah [b6] Santos, Michael (FNIH) [T] [b6] Shen,
 Yuan Li (FDA/CDER) [b6] Stein, Peter (FDA/CDER) [b6] Higgs, Elizabeth
 [b6] Koroshetz, Walter [b6] Farley, John [b6]
 [b6] Qashu, Felicia [b6] Burgess,
 Timothy [b6] Reineck, Lora [b6] Aggarwal, Neil [b6]

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Thanks,
Francis

Francis Collins, MD, PhD
NIH Director

From: Mark Eisner [b6]
Sent: 5/14/2020 3:05:28 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: Re: Time sensitive: Making your ACTIV Participation Public

Hi Francis,

I agree to make my participation public

Mark

Mark D. Eisner, MD, MPH
Senior Vice President, Product Development Immunology, Infectious Disease, and Ophthalmology
Genentech, Inc., a member of the Roche Group
Telephone: [b6] Mobile: [b6]

For administrative assistance, please contact Mary Biggs at:
email: [b6] telephone: [b6]

On Thu, May 14, 2020 at 8:00 AM Collins, Francis (NIH/OD) [E] [b6] wrote:

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.**

Thanks,

Francis

Francis S. Collins, MD, PhD
NIH Director

From: Tartaglia, Jim /US [b6]
Sent: 5/14/2020 3:16:10 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Dear Dr. Collins: I agree to be listed on the web site as part of the ACTIV Team. Best regards. Jim

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 11:00 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Myles, Renate (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: [EXTERNAL] Time sensitive: Making your ACTIV Participation Public

EXTERNAL : Real sender is [b6]

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

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Thanks,
Francis

Francis S. Collins, MD, PhD
NIH Director

From: Draghia Akli, Ruxandra [JRDUS] [b6]
Sent: 5/14/2020 3:26:27 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Dear Francis – thank you for reaching out.

Yes, it is a privilege to be able to participate on the ACTIV working group, and my name can be included in the posting on the web.

Looking forward to the results, and to delivering solutions to patients. Kind regards, Ruxandra

Ruxandra Draghia-Akli, MD, PhD
Global Head
Global Public Health R&D



Mobile: [b6]
[b6]
www.janssen.com

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From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 11:00 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Myles, Renate (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: Time sensitive: Making your ACTIV Participation Public

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COLL0000009502

send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.

Thanks,
Francis

Francis S. Collins, MD, PhD
NIH Director

From: Amanda Peppercorn [REDACTED] b6
Sent: 5/14/2020 3:59:41 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Yes, you may use my name.

Best,

Amanda

Amanda Peppercorn, M.D.
GSK Research & Development
mobile [REDACTED] b6
email [REDACTED] b6

From: Collins, Francis (NIH/OD) [E] [REDACTED] b6
Sent: Thursday, May 14, 2020 11:00 AM
To: Collins, Francis (NIH/OD) [E] [REDACTED] b6
Cc: Myles, Renate (NIH/OD) [E] [REDACTED] b6; Meltzer, Abbey (FNIH) [T] [REDACTED] b6; Wholley, David (FNIH) [T] [REDACTED] b6
Subject: Time sensitive: Making your ACTIV Participation Public

EXTERNAL

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Thanks,
Francis

Francis S. Collins, MD, PhD
NIH Director

COLL0000009500-2440873

GSK monitors email communications sent to and from GSK in order to protect GSK, our employees, customers, suppliers and business partners, from cyber threats and loss of GSK Information. GSK monitoring is conducted with appropriate confidentiality controls and in accordance with local laws and after appropriate consultation.

From: Laura Resnansky [b6]
Sent: 5/14/2020 4:07:32 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: Re: Time sensitive: Making your ACTIV Participation Public

Hi Francis,

I am happy to be listed on the web site.

Best,
Laura

*Laura Resnansky
Therapeutic Area Global Head
Immunology, Infectious Diseases, Ophthalmology and Neuroscience (I2ON)
mobile [b6]*

On Thu, May 14, 2020 at 8:00 AM Collins, Francis (NIH/OD) [E] [b6] wrote:

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.**

Thanks,
Francis

COLL0000009522

Francis S. Collins, MD, PhD

NIH Director

From: Mike Poole [b6]
Sent: 5/14/2020 4:11:07 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: Re: Time sensitive: Making your ACTIV Participation Public

I agree.

Mike Poole, MD FACP
COVID-19 Therapeutics Accelerator
Bill and Melinda Gates Foundation

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 8:00 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Myles, Renate (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: Time sensitive: Making your ACTIV Participation Public

Dear ACTIV Colleagues:

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Thanks,
Francis

Francis S. Collins, MD, PhD
NIH Director

From: Srinivasan, Badhri [b6]
Sent: 5/14/2020 4:44:17 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: Re: Time sensitive: Making your ACTIV Participation Public

Dear Francis,

Thank you for the email and for checking with us.

I agree to be listed on the web site as part of the ACTIV team.

Regards,

Badhri

On 14 May 2020, at 17:00, Collins, Francis (NIH/OD) [E] [b6] wrote:

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

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Thanks,
Francis

Francis S. Collins, MD, PhD
NIH Director

From: Menon, Sandeep M [b6]
Sent: 5/14/2020 5:30:09 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: Re: [EXTERNAL] Time sensitive: Making your ACTIV Participation Public

Hi Francis

Thanks for checking. I am fine to be included.

Sandeep

Sandeep Menon, PhD, MPH
Senior Vice President and Head of Early Clinical Development, Pfizer Inc
1 Portland Street, Cambridge, MA 02139, USA
Cell: [b6]
Email: [b6]

From: "Collins, Francis (NIH/OD) [E]" [b6]
Date: Thursday, May 14, 2020 at 11:00 AM
To: "Collins, Francis (NIH/OD) [E]" [b6]
Cc: "Myles, Renate (NIH/OD) [E]" [b6], "Meltzer, Abbey (FNIH) [T]" [b6]
"Wholley, David (FNIH) [T]" [b6]
Subject: [EXTERNAL] Time sensitive: Making your ACTIV Participation Public

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Thanks,
Francis

Francis S. Collins, MD, PhD
NIH Director

COLL0000009525

From: Koroshetz, Walter (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E8338DD7CDCD432E986961F1548C5EC6-KOROSHETZW]
Sent: 5/14/2020 6:07:04 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [b6]; Mellors, John W [b6]; Naimish Patel [b6]; Young, John [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [b6]; Keith Gottesdiener [b6]; Elliott Levy [b6]; Wung, Peter /US [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]
CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bafd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: RE: Follow-up Materials to ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting #5-Including New Score Sheet (Agents Added)

My mistake on call today. Now see that tocilizumab binds to both the membrane and the soluble IL6 Receptor. So gets at both modes of signaling.
walter

From: Adam, StaMycey (FNIH) [T] [b6]
Sent: Thursday, April 30, 2020 7:11 PM
To: Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Ruxandra Draghia-Akli [b6]; Mellors, John W [b6]; Naimish Patel [b6]; Colvis, Christine (NIH/NCATS) [E] [b6]; Young, John [b6]; Stein, Peter (FDA/CDER) [b6]; Poole, Mike [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [b6]; Vincent, Michael [b6]; Keith Gottesdiener [b6]; Elliott Levy [b6]; Wung, Peter /US [b6]; Koroshetz, Walter (NIH/NINDS) [E] [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6]; Carlos O Garner [b6]
Cc: Elizabeth Kim <elkim@deloitte.com>; Menetski, Joseph (FNIH) [T] [b6]; Alvarez, Rosa Maria [b6]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [b6]; Ward, Jackie (NIH/NINDS) [E] [b6]
Subject: RE: Follow-up Materials to ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting #5-Including New Score Sheet (Agents Added)

Hi All,

This is the second email. It has the anticoag information.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Adam, Stacey (FNIH) [T]

Sent: Thursday, April 30, 2020 7:05 PM

Subject: Follow-up Materials to ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting #5-Including New Score Sheet (Agents Added)

Importance: High

Dear TX-Clinical Agent Prioritization Subgroup,

I appreciate the candid and productive meeting that we had today. All your feedback is very helpful to refine our process for the next time.

For all of you working on scoring right now, please find attached a number of pieces of information that maybe helpful. Some if this some of your groups may have received before, however, I wanted to share it with the whole group for transparency and for having all of our reference data in one place. The information you will find attached is:

1. The summary spreadsheets for the agents in the host targeted category that have been added from the R&D Consortium group + 1 for [b4] as it was requested. (one note, the group shared with us [b4] is likely be tested in a few other trials, so that may need to be considered)
2. Articles on the evolving thrombosis issue that doctors are trying to deal with on the front lines. These were previously shared with the Symptomatic/Supportive therapy group.
3. An article relevant to immune modulator use in COVID-19.
4. Articles for the Antiviral group on some preclinical testing work.
5. Also for the antiviral group, the TX-Preclinical team also just sent this link with access to more screening data, which should contain all but [b4]
 - a. "All of these compounds except [b4] are part of the ReFrame library and have been tested in a SARS-CoV-2 Vero-GFP CPE assay and posted at the ReFrame database here <https://reframedb.org/assays/A00440>. You can create an account for free and search the data."

Please find attached the updated spreadsheet with all the new relevant compounds added for the groups to vote on. These new compounds for your groups are highlighted in green.

Finally, please find below the captured action items and key takeaways from the meeting.

Action Items

Action Items	
Information	POC

1	Provide Review Committee members with 5 compounds for review, along with factsheets from the R&D Consortium	Keith Gottesdiener & Elliott Levy / Stacey Adam
2	Send updated score sheets	Stacey Adam
3	Agent Prioritization Review Committee members (immunomodulators) score additional agents that have been added from the R&D Consortium list Getting standardized, reliable data on the agents	AP Sub Group Members
4	<ul style="list-style-type: none"> Trans-NIH information, intramural and extramural Mike Poole, Gates Foundation 	Stacey Adam / Ruxandra Draghia-Akli
5	Ask Preclinical Working Group (R&D members) for relevant data on agents if available	Joe Menetski
6	Get data on antivirals from NIAID and NCATS	Sarah Read/Christine Colvis

Key Takeaways

- We are re-evaluating our list for scoring and adding other agents that were inadvertently left out
- We will not go back and re-evaluate the triage list.
- Sub Group Members voicing concern on lack of confidence in agents they've had to score. More research needed on drugs to understand whether these are worth putting into clinical trials. Need for more data.
- Suggested need to understand value of the agents we are evaluating over remdesivir.

For reference tomorrow, please find attached the summary from yesterday's meeting and the agenda for tomorrow's meeting.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health

Direct: b6 | Mobile: b6

fnih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Wung, Peter /US [b6]
Sent: 5/14/2020 6:24:49 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Dear Francis,

Thank you for including me in this important endeavor with the NIH.

I am comfortable with my name listed on the website.

Regards,
Peter

Peter K. Wung, MD, MHS, FACR

AVP, Global OMD Lead I&I
Clinical Sciences & Operations | Research & Development

55 CORPORATE DRIVE - BRIDGEWATER - New Jersey 08807

Cell: [b6]
[b6]



From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 10:00 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Myles, Renate (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: [EXTERNAL] Time sensitive: Making your ACTIV Participation Public

EXTERNAL : Real sender is [b6]

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on

COLL0000009529

ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.**

Thanks,
Francis

Francis S. Collins, MD, PhD
NIH Director

From: Tountas, Karen (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
Sent: 5/14/2020 8:36:15 PM
To: Vincent, Mike [b6]; Bascles, Lionel [b6] Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [b6] Desrosiers, Betsy [b6] Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshov, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshovj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; King, James (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce1f3853e43d4463a04f7d74992f96ac-James.King.]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura [b6]; Srinivasan, Badhri [b6] Wachtel, Jonathan [jwachtel@deloitte.com]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]
CC: Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Kenny, Dermot [b6]; Garner, Carlos [b6] Mensah, George (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Weinmann, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [b6]; Jansen, Kathrin [b6] Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [b6]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [marganderson@deloitte.com]; Carluccio, Dana [b6] Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny [b6] James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [b6]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a27ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveson, Nancy [b6] Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative

Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Criffield, Robin
[b6]; Hamilton, Nancy [b6]; Minnich, Beth
[b6]; Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Stratton, Benjamin
[bstratton@DELOITTE.com]; Tolman, Brett [btolman@deloitte.com]; Victoria Davey [/o=ExchangeLabs/ou=Exchange
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da];
Jintanat Ananworanich [b6]

Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting
Attachments: Clinical Trial Capacity Working Group Meeting Agenda_05152020.pdf
Location: [b6]

Start: 5/15/2020 1:00:00 PM
End: 5/15/2020 2:00:00 PM
Show Time As: Tentative

Recurrence: Weekly
every Tuesday and Friday from 9:00 AM to 10:00 AM
Required Attendees: Vincent, Mike; Bascles, Lionel; Stein, Peter (FDA/CDER); Cohen, Myron; Corey, Larry; Desrosiers, Betsy; Dickens, Jim
(NIH/NCATS) [C]; Doroshov, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; King, James; Kurilla, Mike; Nayak,
Seema (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Payton, Manzone; Resnansky, Laura; Srinivasan, Badhri; Wachtel,
Jonathan; Qashu, Felicia
Optional Attendees: Sizemore, Christine (NIH/FIC) [E]; Kenny, Dermot; Garner, Carlos; Mensah, George; Weinmann, Gail; Colvis, Christine
(NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John;
Adam, Stacey (FNIH) [T]; Anderson, Margaret; Carluccio, Dana; Cheryl (FNIH) Melencio [T] [b6]
Francis Collins; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos,
Michael (FNIH); Tuveson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Minnich, Beth;
Rebecca (NIH/NCATS) Katz [E] [b6] Stratton, Benjamin; Tolman, Brett; Davey, Victoria; Jintanat
Ananworanich

Dear Colleagues, Attached is the agenda for this call. Talk with you then. Karen

ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines

Dear Clinical Trial Capacity Working Group members,

In anticipation of this working group making rapid progress on identified action items and other activities, the co-chairs have agreed that it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify areas of need, and to determine next steps. We ask that you make every effort possible to join each of these meetings, but understand that at times you may have competing priorities. To place a hold on your calendar, please accept this meeting invite with a response; later you can decline an individual meeting if you have a conflict.

An agenda and other meeting materials, as needed, will be distributed prior to each call.

With best regards,
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health

Join Zoom Meeting

[b6]

Meeting ID: [b6]

APAR0000017178

Password: **b6**

One tap mobile

b6	US (Chicago) US (New York)
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Dial by your location

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	US (New York)
	US
	US (Houston)
	US (San Jose)
	US (San Jose)
US	

Meeting ID: **b6**

Password: **b6**

Find your local number: **b6**

From: Menetski, Joseph (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 5/14/2020 9:01:45 PM
To: [b6] Tomas Cihlar [b6]
USARMY [b6] (USA) [b6]
[b6]
[b6] Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
[b6] Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
[b6] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras];
[b6] Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [b6]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]
CC: Diamond, Michael [b6] Rodriguez, Robin D [b6] Hall, Matthew (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c76a7b2623714aaaa095fda97973f5e6-hallma_b4f6]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [b6]; Hughes, Eric [b6]; Jansen, Kathrin [b6]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Kim, Elizabeth [elkim@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Wachtel, Jonathan [jwachtel@deloitte.com]; Prabhavathi Fernandes [b6]; Rose Li [b6]; Dana Carluccio [b6] Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Dave Frankowski [b6] Baric, Toni C [b6] Stratton, Benjamin [bstratton@DELOITTE.com]

Subject: RE: ACTIV Preclinical working group (Tuesday meeting)

Attachments: 2020-05-12_Preclinical_WG_Summary_RLA_d3.docx

Dear preclinical working group and invitees,

Please find the minutes from our meeting on Tuesday. I apologize for being late (my fault, I am afraid). We look forward to seeing you all tomorrow. Please let me know if you have any questions or modifications to these.

Best regards,
Joe

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T]

Sent: Tuesday, April 14, 2020 6:43 PM

To: [b6] Tomas Cihlar; [b6] USARMY [b6] [b6] (USA); Menetski, Joseph (FNIH) [T]; [b6]

b6

b6

Parker, Ashley

(NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; [b6] Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]

Cc: Diamond, Michael; Rodriguez, Robin D; Hall, Matthew (NIH/NCATS) [E]; Florence, Clint (NIH/NIAID) [E]; Lowy, Douglas (NIH/NCI) [E]; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Dave Frankowski; Baric, Toni C; Stratton, Benjamin

Subject: ACTIV Preclinical working group (Tuesday meeting)

When: Tuesday, May 12, 2020 2:00 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: [b6]

Holding time

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting

b6

Meeting ID: [b6]

Password: [b6]

One tap mobile

b6

US (Chicago)
US (New York)

Dial by your location

b6

US (Chicago)
US (New York)
US
US (Houston)
US (San Jose)
US (San Jose)
US

Meeting ID:

b6

Password:

b6

Find your local number:

b6

From: Penny Heaton [b6]
Sent: 5/14/2020 10:40:17 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Dear All,

Yes – I agree to be listed on the web site as part of the ACTIV team.

Best,

Penny

Penny M. Heaton, MD
Chief Executive Officer
Bill & Melinda Gates Medical Research Institute
245 Main Street, Cambridge, MA 02142

T +1 857 301 9404 M [b6]
E [b6]

Mary Burke
Executive Assistant to the CEO
Bill & Melinda Gates Medical Research Institute
245 Main Street, Cambridge, MA 02142

M [b6]
E [b6]

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 11:00 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Myles, Renate (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: Time sensitive: Making your ACTIV Participation Public

Attention: This message was sent from an external domain.

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please**

send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.

Thanks,
Francis

Francis S. Collins, MD, PhD
NIH Director

From: Patel, Naimish /US [b6]
Sent: 5/15/2020 2:49:06 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: Time sensitive: Making your ACTIV Participation Public

Dear Francis,

I would be happy to have my name listed on the website.

Best,
Naimish

From: "Collins, Francis (NIH/OD) [E]" [b6]
Date: Thursday, May 14, 2020 at 11:03 AM
To: "Collins, Francis (NIH/OD) [E]" [b6]
Cc: "Myles, Renate (NIH/OD) [E]" [b6], "Meltzer, Abbey (FNIH) [T]" [b6], "Wholley, David (FNIH) [T]" [b6]
Subject: [EXTERNAL] Time sensitive: Making your ACTIV Participation Public

EXTERNAL : Real sender is: [b6]

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.**

Thanks,
Francis

Francis S. Collins, MD, PhD
NIH Director

COLL0000009570

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 5/15/2020 2:50:21 AM
To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Allen-Gifford, Patrice (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=67262490d6d441b48efec1aff0700250-allengiffor]
CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wooldridge, Shannon (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=385b0c281f104789873e956dc91b7c06-burdense]; Pollock, Rachel (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4887cb3513e242dfa7d2df712dcc6d6a-pollockrc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

I'm agreeing with that.

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 10:50 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Allen-Gifford, Patrice (NIH/OD) [E] <patrice.allen-[b6]>
Cc: Parker, Ashley (NIH/OD) [E] [b6]; Wooldridge, Shannon (NIH/OD) [E] [b6]; Pollock, Rachel (NIH/OD) [E] [b6]; Melencio, Cheryl (FNIH) [T]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Can we remove the NIHers? I don't think we need their permissions, right?

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 10:49 PM
To: Myles, Renate (NIH/OD) [E] [b6]; Allen-Gifford, Patrice (NIH/OD) [E] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]; Wooldridge, Shannon (NIH/OD) [E] [b6]; Pollock, Rachel (NIH/OD) [E] [b6]; Melencio, Cheryl (FNIH) [T]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Yes, please send an update in the AM. And then I will appreciate a concatenated set of e-mail addresses for the tardy ones.
FC

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 10:44 PM
To: Allen-Gifford, Patrice (NIH/OD) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]; Wooldridge, Shannon (NIH/OD) [E] [b6]; Pollock, Rachel (NIH/OD) [E] [b6]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

By my count, we are still awaiting 39 responses, including 10 from NIH staff (highlighted in yellow). I don't think we really need to get permission from the NIHers, do we?

We gave folks until noon tomorrow, but you may want to send another email out in the morning to the non-NIH folks. I can give you an updated count in the morning.

William Pao, M.D., Ph.D.

Head of Pharma Research and Early Development (pRED)
Roche

Annaliesa Anderson, Ph.D., FAAM

Vice President and Chief Scientific Officer, Bacterial Vaccines
Pfizer

Ralph Baric, Ph.D.

William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology
Professor, Department of Microbiology and Immunology
University of North Carolina, Gillings School of Global Public Health

Marc Charette, Ph.D.

Program Director
Division of Cardiovascular Diseases
National Heart, Lung, and Blood Institute, NIH

Damon Deming, Ph.D.

Virologist, Division of Antiviral Products, Office of New Drugs
U.S. Food and Drug Administration

Greg Gatto, Ph.D.

Drug Development Regulatory Project Leader
RTI International

Jay Grobler, Ph.D.

Director, Infectious Disease Biology
Merck & Co., Inc.

Judith Hewitt, Ph.D.

Deputy Director, Office of Biodefense, Research Resources and Translational Research
National Institute of Allergy and Infectious Diseases, NIH

Samantha Jonson, M.P.S.

Special Assistant to the Director
National Center for Advancing Translational Sciences, NIH

Cat Lutz, Ph.D.

Senior Director, Mouse Repository & In Vivo Pharmacology, Rare and Orphan Disease Center
The Jackson Laboratory

Elizabeth Ottinger, Ph.D.

Senior Program Manager, Division of Preclinical Innovation
National Center for Advancing Translational Sciences, NIH

David Payne, Ph.D.

Vice President & Head, Medicine Opportunities Research Unit
GlaxoSmithKline

Louise Pitt, Ph.D.

Director, Center for Aerobiological Sciences
United States Army Medical Research Institute of Infectious Diseases

Srinivas Rao, DVM, Ph.D.

Global Head, Translational In Vivo Models Global Research Platform
Sanofi

Jay Rappaport, Ph.D.

Professor of Microbiology and Immunology
Director and Chief Academic Officer
Tulane University National Primate Research Center

Frank Stegmeier, Ph.D.

Chief Scientific Officer
KSQ Therapeutics

John Young, Ph.D.

Global Head Infectious Diseases and Vice President
Roche

Sylva Collins, Ph.D.

Director, Office of Biostatistics
U.S. Food and Drug Administration

Judith Currier, M.D.

Professor of Medicine
University of California Los Angeles
Division of Infectious Diseases
Chair, AIDS Clinical Trial Group (ACTG)

John Farley, M.D., M.P.H.

Director, Office of Infectious Diseases
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Elliot Levy, M.D.

Senior Vice President, Global Development
Amgen

Naimish Patel, M.D.

Head of Global Development, Immunology and Inflammation Therapeutic Area
Sanofi Genzyme

Yves Rosenberg, M.D., MPH

Branch Chief, Atherothrombosis and Coronary Artery Disease Branch
National Heart, Lung, and Blood Institute, NIH

Peter Stein, M.D.

Director of Office of New Drugs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Lionel Bascles, Ph.D.

Senior Vice President, Global Head of Clinical Sciences & Operations
Sanofi

Jim Doroshow, M.D.

Director, Division of Cancer Treatment and Diagnosis
National Cancer Institute, NIH

Carlos Garner, Ph.D.

Vice President, Global Regulatory Affairs
Eli Lilly and Company

Seema Nayak, M.D.

Director, Office of Clinical Research Resources
National Institute of Allergy and Infectious Diseases, NIH

Manizhe Payton, MPH

Director, Office of Clinical Site Oversight, DAIDS
National Institute of Allergy and Infectious Diseases, NIH

Christine Sizemore, Ph.D.

Director, Division of International Relations
Fogarty International Center, NIH

Peter Stein, M.D.

Director of Office of New Drugs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Beth Bell, M.D., MPH

Clinical Professor, Global Health
University of Washington

Emilio Emini, Ph.D.

Director, TB & HIV Program
Bill & Melinda Gates Foundation

Emmanuel Hanon, Ph.D.

Senior Vice President of Vaccines Research and Development
GlaxoSmithKline

Kathrin Jansen, Ph.D.

Senior Vice President and Head of Vaccine Research and Development
Pfizer

Antonio Lanzavecchia, M.D.

Senior Vice President and Senior Research Fellow

Vir Biotechnology, Inc.
Director, Institute for Research in Biomedicine, Bellinzona, Switzerland

John Mascola, M.D.

Director, Dale and Betty Bumpers Vaccine Research Center
National Institute of Allergy and Infectious Diseases, NIH

Nancy Messonnier, M.D.

Director, Center for the National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention

Jonathan Seals, Ph.D.

Director, Strategic Science and Technology
Biomedical Advanced Research and Development Authority

From: Allen-Gifford, Patrice (NIH/OD) [E] [b6]

Sent: Thursday, May 14, 2020 1:27 PM

To: Collins, Francis (NIH/OD) [E] [b6]

Cc: Myles, Renate (NIH/OD) [E] [b6] Parker, Ashley (NIH/OD) [E] [b6]

Wooldridge, Shannon (NIH/OD) [E] [b6] Pollock, Rachel (NIH/OD) [E]

[b6]

Subject: RE: Time sensitive: Making your ACTIV Participation Public

Certainly. We will put the responses in a subfolder immediately.

From: Collins, Francis (NIH/OD) [E] [b6]

Sent: Thursday, May 14, 2020 1:03 PM

To: Allen-Gifford, Patrice (NIH/OD) [E] [b6]

Cc: Myles, Renate (NIH/OD) [E] [b6] Parker, Ashley (NIH/OD) [E] [b6]

Subject: FW: Time sensitive: Making your ACTIV Participation Public

These are great responses, but my inbox is overflowing. Can you set up a separate file to put all of the responses that have this same subject line?

From: Bozzette, Sam (NIH/NCATS) [E] [b6]

Sent: Thursday, May 14, 2020 11:09 AM

To: Collins, Francis (NIH/OD) [E] [b6]

Cc: Myles, Renate (NIH/OD) [E] [b6] Meltzer, Abbey (FNIH) [T] [b6] Wholley, David

(FNIH) [T] [b6]

Subject: RE: Time sensitive: Making your ACTIV Participation Public

I would be pleased to be listed under Therapeutics-Clinical WG:

Sam Bozzette, MD, PhD
CMO, NCATS

Thank you

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 11:00 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Myles, Renate (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: Time sensitive: Making your ACTIV Participation Public

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.**

Thanks,
Francis

Francis S. Collins, MD, PhD
NIH Director

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/15/2020 3:19:38 AM
To: Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [b6]; Keith Gottesdiener [b6]; Elliott Levy [b6]; Wung, Peter /US [b6]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [b6]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Rose Li Central Account [FNIH@roseliassociates.com]
Subject: Initial Follow-up to ACTIV TX-Clinical Agent Prioritization Subgroup #10
Attachments: Therapeutic information request form-v6.docx; ACTIV_Therapeutics-Clinical_AP Sub-Group Meeting 14May2020_Key Takeaways.pdf; ACTIV_Therapeutics Clinical Agent Prioritization Scoring Guide_v3.pptx

Dear ACTIV TX-Clinical Agent Prioritization Subgroup,

Please find attached the follow up materials from today's meeting.

The materials include:

1. A quick capture of action items and major decisions from the meeting. **A formal summary will follow tomorrow.**
2. Updated Agent Prioritization Criteria Slides with the changes suggested today made. **Please review for final approval.**
3. An updated version of the company survey/RFI that we would use for multiple purposes: 1) to do specific information solicitation on high priority compounds that this group wishes to score, 2) to have any company or group who has submitted an agent for your consideration populate this so we are working on the right data, and 3) potentially to do a broad company solicitation of additional compounds that the companies would like to have considered for testing.

Please review and let us know if this reflects the changes suggested and that it has all the questions you would want to see to ensure that we will have the right data to review for our high priority compounds. We have worked to balance being thorough with making sure it is not too onerous for a company to fill out. Please let us know if you have any amendments or additions.

Thank you for your review of these materials.

Thanks,

Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Foundation for the National Institutes of Health

Direct: [b6] | Mobile: [b6]

fnih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 5/15/2020 8:43:16 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: RE: Meeting notes from yesterday's ACTIV EC meeting

I think it's OK, but given the way in which the previous distributions ended up in the hands of Jon Cohen, a specific reminder to the WG members that these are confidential would be a good thing.

FC

From: Wholley, David (FNIH) [T] [b6]
Sent: Thursday, May 14, 2020 11:35 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Freire, Maria (FNIH) [T] [b6]
Subject: FW: Meeting notes from yesterday's ACTIV EC meeting

I don't see any problem with this, do you? Each page is marked Confidential and Predecisional.

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Thursday, May 14, 2020 10:54 PM
To: Wholley, David (FNIH) [T] [b6]
Subject: RE: Meeting notes from yesterday's ACTIV EC meeting

Hi David,

Am I allowed to share the notes with my WG? They asked today if they would be shared since the group was discussing our letter.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [b6] | Mobile: [b6]

From: Wholley, David (FNIH) [T] [b6]
Sent: Thursday, May 14, 2020 10:50 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Dolsten, Mikael [b6]; Fauci, Anthony (NIH/NIAID) [E] [b6]; Gibbons, Gary (NIH/NHLBI) [E] [b6]; Pao, William [b6]; Stoffels, Paul [b6]; Woodcock, Janet (FDA/CDER) [b6]
Cc: Colvis, Christine (NIH/NCATS) [E] [b6]; Desrosiers, Betsy [b6]; Hughes, Eric [b6]; Jansen, Kathrin <[b6]> [b6]; Kurilla, Michael (NIH/NCATS) [E] [b6]; Lowy, Douglas (NCI) [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Young, John [b6]; Anderson, James (NIH/OD) [E] [b6]

[b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Lane, Cliff (NIH/NIAID) [E]
[b6]; Parker, Ashley (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E]
[b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Adam, Stacey (FNIH) [T]
[b6]; Alvarez, Rosa <rosalvarez@deloitte.com>; Anderson, Margaret <marganderson@deloitte.com>;
Elsaid, Olivia <oelsaid@deloitte.com>; Gonzalez, Nina <ningonzalez@deloitte.com>; James, Stephanie (FNIH) [T]
[b6]; Kim, Elizabeth <elkim@deloitte.com>; Menetski, Joseph (FNIH) [T] [b6] Santos,
Michael (FNIH) [T] [b6]; Stratton, Ben <bstratton@deloitte.com>; Tolman, Brett
<btolman@deloitte.com>; Tountas, Karen (FNIH) [T] [b6]; Wachtel, Jonathan
<jwachtel@deloitte.com>; Wholley, David (FNIH) [T] [b6]
Subject: Meeting notes from yesterday's ACTIV EC meeting

Dear ACTIV Executive Committee Members, Working Group Co-Chairs and guest participants:

Here are the complete notes, including action items, from yesterday's ACTIV EC meeting. Please let me know if there is anything we may have missed. In addition, I am forwarding at Janet Woodcock's request slides she mentioned describing the global landscape of studies on convalescent plasma and hyperimmune globulin.

I look forward to continued discussions on our next EC call, scheduled for next Wednesday, May 20.

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

[b6]
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 5/15/2020 9:02:26 AM
To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]
Subject: FW: Time sensitive: Making your ACTIV Participation Public

From: Emmanuel Hanon [b6]
Sent: Friday, May 15, 2020 2:32 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: Re: Time sensitive: Making your ACTIV Participation Public

Ok for me
R
M

From: "Collins, Francis (NIH/OD) [E]" [b6]
Date: Thursday, 14 May 2020 at 17:00
To: "Collins, Francis (NIH/OD) [E]" [b6]
Cc: "Myles, Renate (NIH/OD) [E]" [b6] "Meltzer, Abbey (FNIH) [T]" [b6]
"Wholley, David (FNIH) [T]" [b6]
Subject: Time sensitive: Making your ACTIV Participation Public

EXTERNAL

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

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Thanks,
Francis

Francis S. Collins, MD, PhD
NIH Director

GSK monitors email communications sent to and from GSK in order to protect GSK, our employees, customers, suppliers and business partners, from cyber threats and loss of GSK Information. GSK monitoring

COLL0000011045

is conducted with appropriate confidentiality controls and in accordance with local laws and after appropriate consultation.

Sent: 5/15/2020 11:49:33 AM
To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]
CC: Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
Subject: RE: PLEASE READ: Draft Email to Collect Communication Contact Information
Attachments: RE: List -- just copy and paste in bcc. lists of April 3 plus working groups

These list were compiled yesterday morning by FNIH without any names, only emails. I wanted to double check the emails FNIH provided with names of the reps on the 4 ACTIV WGs along with the reps who participated in the April 3rd PPP meeting.

I found 8 emails that were missing and shared this with FC yesterday afternoon. Andy Plump was among the 8 which explains why the email was missing.

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Thursday, April 16, 2020 8:15 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Wolinetz, Carrie (NIH/OD) [E]
Subject: RE: PLEASE READ: Draft Email to Collect Communication Contact Information

I used the master list that you sent to him earlier in the week and Takeda wasn't in there. I never received an updated version of the master list.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, April 16, 2020 8:14 AM
To: Myles, Renate (NIH/OD) [E] [b6]
Cc: Wolinetz, Carrie (NIH/OD) [E]
Subject: RE: PLEASE READ: Draft Email to Collect Communication Contact Information

Here is the updated list – seems FC used your emails and not the master list.

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Thursday, April 16, 2020 8:10 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Wolinetz, Carrie (NIH/OD) [E]
Subject: RE: PLEASE READ: Draft Email to Collect Communication Contact Information

I pulled the names from the attached that you sent earlier in the week. There isn't a Takeda contact on this list. Would you send it to me?

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, April 16, 2020 8:03 AM
To: Myles, Renate (NIH/OD) [E] [b6]
Cc: Wolinetz, Carrie (NIH/OD) [E]
Subject: RE: PLEASE READ: Draft Email to Collect Communication Contact Information

Good morning Renate,

Our rep at Takeda, Andy Plump is included on the master list. I am confirming with Francis that he used our master list for his email that went out last night – **I should be able to confirm this for you this morning.**

I hope you are staying safe and healthy; maybe even getting some rest in between the constant COVID activities.

Thanks,
Ashley

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Thursday, April 16, 2020 7:14 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Wolinetz, Carrie (NIH/OD) [E]
Subject: FW: PLEASE READ: Draft Email to Collect Communication Contact Information
Importance: High

Hi Ashley:

I'm not sure if Francis added a Takeda contact to his email. I could not find one on the master contact list. I have not heard from their organizations yet. Would you let me know if you provided that to him last night or if they are missing from this email? Need to send it to this group this morning.

Thanks,
Renate

From: Myles, Renate (NIH/OD) [E]
Sent: Wednesday, April 15, 2020 9:11 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Wood, Gretchen (NIH/OD) [E] [b6]; McManus, Ayanna (NIH/OD) [E]
[b6]; Burklow, John (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: PLEASE READ: Draft Email to Collect Communication Contact Information
Importance: High

Hi Francis:

We need to collect the communication contacts from the partner organizations so we can share the release with them for review. Below is 1) a draft email for you to send to the company participants, 2) the contacts for the companies we list in the release except for Takeda (I could not find a Takeda contact on the master list; hoping Ashley can provide); 3) those who should be copied (feel free to add others).

Dear ACTIV colleagues:

As I mentioned earlier today, we would like to announce the plans for a public-private partnership as expeditiously as possible. Please provide the name of the most appropriate communication contact from your company so that we may share a draft of the embargoed press release for your review. Please send the contact information to Renate Myles at

[b6]

and Abbey Meltzer [b6] this evening, if possible.

BCC:

[b6]

b6

CC:

b6

Thanks,
Renate

From: Pollock, Rachel (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4887CB3513E242DFA7D2DF712DCC6D6A-POLLOCKRC]
Sent: 5/15/2020 12:08:18 PM
To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]
CC: Allen-Gifford, Patrice (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=67262490d6d441b48efec1aff0700250-allengiffor]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wooldridge, Shannon (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=385b0c281f104789873e956dc91b7c06-burdense]
Subject: RE: Time sensitive: Making your ACTIV Participation Public
Attachments: Time sensitive: Making your ACTIV Participation Public

Renate – in case it is helpful, attached is what I believe to be the send round email, and which includes the full list of email addresses in the bcc line. CC'ing Ashley to confirm.

Rachel Pollock

O: [b6]
C: [b6]

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Friday, May 15, 2020 7:53 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Allen-Gifford, Patrice (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Wooldridge, Shannon (NIH/OD) [E] [b6]; Pollock, Rachel (NIH/OD) [E] [b6]
Subject: FW: Time sensitive: Making your ACTIV Participation Public

Hi Francis:

Below is the list of 23 vpeople who have not yet responded to your email. I cross referenced these names with the email list that Ashely sent and pulled addresses from that list. I didn't find emails for a number of these people, but I know there was a second round that went out using emails I don't have. Hoping Ashley can provide the missing emails.

[b6]

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Professor, Department of Microbiology and Immunology
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Centers for Disease Control and Prevention

b6

Jonathan Seals, Ph.D.

Director, Strategic Science and Technology
Biomedical Advanced Research and Development Authority

From: Collins, Francis (NIH/OD) [E]

b6

Sent: Thursday, May 14, 2020 11:00 AM

To: Collins, Francis (NIH/OD) [E]

b6

Cc: Myles, Renate (NIH/OD) [E]

; Meltzer, Abbey (FNIH) [T]

b6

Wholley, David

(FNIH) [T]

b6

Subject: Time sensitive: Making your ACTIV Participation Public

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.**

Thanks,
Francis

Francis S. Collins, MD, PhD
NIH Director

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/15/2020 12:16:23 PM
To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]
CC: Pollock, Rachel (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4887cb3513e242dfa7d2df712dcc6d6a-pollockrc]; Allen-Gifford, Patrice (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=67262490d6d441b48efec1aff0700250-allengiffor]; Wooldridge, Shannon (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=385b0c281f104789873e956dc91b7c06-burdense]
Subject: Re: Time sensitive: Making your ACTIV Participation Public

Renate, we are adding the emails you do not have — these were sent later on yesterday.

Ashley Parker, Ph.D.
Special Assistant to Acting Chief of Staff to the NIH Director
Office of the Director | National Institutes of Health
Tel: [b6]

On May 15, 2020, at 8:13 AM, Myles, Renate (NIH/OD) [E] [b6] wrote:

Thanks, Rachel. Jay Grobler just responded, so I've removed him from the list. Will you be sending it out this morning?

From: Pollock, Rachel (NIH/OD) [E] [b6]
Sent: Friday, May 15, 2020 8:08 AM
To: Myles, Renate (NIH/OD) [E] [b6]
Cc: Allen-Gifford, Patrice (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Wooldridge, Shannon (NIH/OD) [E] [b6]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Renate – in case it is helpful, attached is what I believe to be the send round email, and which includes the full list of email addresses in the bcc line. CC'ing Ashley to confirm.

Rachel Pollock
O: 301.827.8362
C: [b6]

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Friday, May 15, 2020 7:53 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Allen-Gifford, Patrice (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Wooldridge, Shannon (NIH/OD) [E] [b6]; Pollock, Rachel (NIH/OD) [E] [b6]
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Centers for Disease Control and Prevention

b6

Jonathan Seals, Ph.D.

Director, Strategic Science and Technology

Biomedical Advanced Research and Development Authority

From: Collins, Francis (NIH/OD) [E]

b6

Sent: Thursday, May 14, 2020 11:00 AM

To: Collins, Francis (NIH/OD) [E]

b6

Cc: Myles, Renate (NIH/OD) [E]

Meltzer, Abbey (FNIH) [T]

b6

Wholley, David (FNIH) [T]

b6

Subject: Time sensitive: Making your ACTIV Participation Public

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

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Thanks,
Francis

Francis S. Collins, MD, PhD
NIH Director

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/15/2020 12:29:37 PM
To: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Thanks!!

From: Brodd, Lauren (NIH/OD) [E] [b6]
Sent: Friday, May 15, 2020 8:21 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Hi Ashley,

See list below with emails added. Let me know if you need anything else.

Thanks,

Lauren

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Friday, May 15, 2020 8:08 AM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: Re: Time sensitive: Making your ACTIV Participation Public

Thanks, Lauren!

Ashley Parker, Ph.D.
Special Assistant to Acting Chief of Staff to the NIH Director
Office of the Director | National Institutes of Health
Tel [b6]

On May 15, 2020, at 8:07 AM, Brodd, Lauren (NIH/OD) [E] [b6] wrote:

Sure I'll look on your excel sheets for these emails.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Friday, May 15, 2020 8:04 AM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: Re: Time sensitive: Making your ACTIV Participation Public

Hi Lauren,

Can you help by adding the missing emails to the folks names below? I would assume this is already done in the revised document?

Thanks,
Ashley

Ashley Parker, Ph.D.
Special Assistant to Acting Chief of Staff to the NIH Director
Office of the Director | National Institutes of Health
Tel: [b6]

Begin forwarded message:

From: "Myles, Renate (NIH/OD) [E]" [b6]
Date: May 15, 2020 at 7:52:35 AM EDT
To: "Collins, Francis (NIH/OD) [E]" [b6]
Cc: "Allen-Gifford, Patrice (NIH/OD) [E]" [b6] "Parker, Ashley (NIH/OD) [E]" [b6], "Wooldridge, Shannon (NIH/OD) [E]" [b6], "Pollock, Rachel (NIH/OD) [E]" [b6]
Subject: FW: Time sensitive: Making your ACTIV Participation Public

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[b6]

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[b6]

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b6

Jonathan Seals, Ph.D.

Director, Strategic Science and Technology

Biomedical Advanced Research and Development Authority

b6

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 11:00 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Myles, Renate (NIH/OD) [E] [b6], Meltzer, Abbey (FNIH) [T]
[b6], Wholley, David (FNIH) [T] [b6]
Subject: Time sensitive: Making your ACTIV Participation Public

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Thanks,
Francis

Francis S. Collins, MD, PhD
NIH Director

Sent: 5/15/2020 12:57:02 PM
To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Allen-Gifford, Patrice (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=67262490d6d441b48efec1aff0700250-allengiffor]; Wooldridge, Shannon (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=385b0c281f104789873e956dc91b7c06-burdense]; Pollock, Rachel (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4887cb3513e242dfa7d2df712dcc6d6a-pollockrc]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Hi Renate,

I've added the emails below but we have a major version control issues. I've been working with Cheryl to receive updates and did not have Sylvia Collins, Beth Bell and Jonathan Seals and apparently they are listed on a separate list the FNIH communications team is tracking and was added later on yesterday.

We can send follow up emails to everyone except for those three – they will need to be contacted. Moving forward, it may be best for you to receive updates from the communications team – FNIH is managing multiple spreadsheets one for the emails Cheryl is managing to schedule meetings and a separate list for the communications office.

Ralph Baric, Ph.D.

William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology
Professor, Department of Microbiology and Immunology
University of North Carolina, Gillings School of Global Public Health

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Biomedical Advanced Research and Development Authority

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From: Myles, Renate (NIH/OD) [E]

b6

Sent: Friday, May 15, 2020 7:53 AM

To: Collins, Francis (NIH/OD) [E]

b6

Cc: Allen-Gifford, Patrice (NIH/OD) [E]

b6

Parker, Ashley (NIH/OD) [E]

b6

Wooldridge, Shannon (NIH/OD) [E]

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Pollock, Rachel (NIH/OD)

[E] b6

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Centers for Disease Control and Prevention

b6

Jonathan Seals, Ph.D.

Director, Strategic Science and Technology

Biomedical Advanced Research and Development Authority

From: Collins, Francis (NIH/OD) [E]

b6

Sent: Thursday, May 14, 2020 11:00 AM

To: Collins, Francis (NIH/OD) [E]

b6

Cc: Myles, Renate (NIH/OD) [E]

Meltzer, Abbey (FNIH) [T]

b6

Wholley, David

(FNIH) [T] b6

Subject: Time sensitive: Making your ACTIV Participation Public

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.**

Thanks,
Francis

Francis S. Collins, MD, PhD
NIH Director

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/15/2020 1:11:03 PM
To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Allen-Gifford, Patrice (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=67262490d6d441b48efec1aff0700250-allengiffor]; Wooldridge, Shannon (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=385b0c281f104789873e956dc91b7c06-burdense]; Pollock, Rachel (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4887cb3513e242dfa7d2df712dcc6d6a-pollockrc]
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Professor, Department of Microbiology and Immunology
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Francis S. Collins, MD, PhD
NIH Director

Sent: 5/15/2020 1:44:15 PM
To: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: FW: Time sensitive: Making your ACTIV Participation Public
Attachments: Leadership _ National Institutes of Health (NIH).pdf

Hi Lauren,

One things that would be helpful – can we cross check the updated list Renate shared with the attached spreadsheet of emails

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Friday, May 15, 2020 9:21 AM
To: Parker, Ashley (NIH/OD) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6]
Cc: Allen-Gifford, Patrice (NIH/OD) [E] [b6]; Wooldridge, Shannon (NIH/OD) [E] [b6]; Pollock, Rachel (NIH/OD) [E] [b6]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Hi Ashley:

Attached is the full list of members currently listed on the website in staging. I received the list from FNIH communications. Please let me know of any changes.

Thanks,
Renate

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Friday, May 15, 2020 9:11 AM
To: Myles, Renate (NIH/OD) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6]
Cc: Allen-Gifford, Patrice (NIH/OD) [E] [b6]; Wooldridge, Shannon (NIH/OD) [E] [b6]; Pollock, Rachel (NIH/OD) [E] [b6]
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Francis S. Collins, MD, PhD
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Sent: 5/15/2020 1:47:20 PM
To: Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Burgess, Timothy [b6] Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [b6] Eisner, Mark [b6] Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Garner, Carl [b6]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Gottesdiener, Keith [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Hughes, Eric [b6]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; LaVange, Lisa [b6]; Levy, Elliot [b6] Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [b6] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [b6] Peppercorn, Amanda [b6] Poole, Mike [b6] Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Tenaerts, Pamela [b6] Wung, Peter [b6]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc8d75f0679648859e1cf101c0943414-adamsj4]; Kim, Elizabeth [elkim@deloitte.com]
Subject: ACTIV EC Meeting Notes from Wednesday
Attachments: 2020-05-13_Executive_Committee_Meeting_Summary 5-14-20 F (002).pdf

Dear ACTIV Therapeutics-Clinical Working Group members:

Please see attached the meeting notes and action items from the ACTIV Executive Committee teleconference held on May 13, the majority of which was focused on reviewing your letter to the Committee. I just sent them to the EC late last night and am happy to share with you. As noted the notes are marked confidential and predecisional; please treat with appropriate discretion and do not distribute further.

APAR0000005403

Thanks,
David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

b6

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/15/2020 2:27:11 PM
To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]
CC: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: RE: Time sensitive: Making your ACTIV Participation Public
Attachments: Leadership _ National Institutes of Health (NIH).pdf; 1-Draft_NIH_ACTIV_Webpage_Content 5.14.2020 w changes updated editsLBAP.docx

Hi Renate,

Sparing FC's inbox and others.

With many thanks to Lauren for helping us with this. Please see edits attached and below – the alphabetizing of the names can be ignored as this is updated in the revised version you've provided.

A few minor edits:

- Co-chairs of the working groups should be identified
- Consistency with MD or M.D.
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Thanks,
Ashley

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Sent: Friday, May 15, 2020 9:21 AM
To: Parker, Ashley (NIH/OD) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6]
Cc: Allen-Gifford, Patrice (NIH/OD) [E] [b6]; Wooldridge, Shannon (NIH/OD) [E] [b6]; Pollock, Rachel (NIH/OD) [E] [b6]
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Hi Ashley:

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[E] b6

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Biomedical Advanced Research and Development Authority

From: Collins, Francis (NIH/OD) [E] [b6]

Sent: Thursday, May 14, 2020 11:00 AM

To: Collins, Francis (NIH/OD) [E]

Cc: Myles, Renate (NIH/OD) [E] [b6] Meltzer, Abbey (FNIH) [T] [b6] Wholley, David (FNIH) [T] [b6]

Subject: Time sensitive: Making your ACTIV Participation Public

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.**

Thanks,
Francis

Francis S. Collins, MD, PhD
NIH Director

From: Sharpless, Norman (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=340F3D07B6644DA7ACA53AB83DC066EF-SHARPLESSNE]
Sent: 5/15/2020 2:37:35 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: standardized immunology assays to facilitate and speed approval of a vaccine against Covid 19

Thx for sending

This is the sort of scientific effort that the NCI wishes to support with the serology centers of excellence that we will be funding, and I will make sure they see our FOAs.

I think having an academic site doing testing for the clinical trials of ACTIV and then holding what I think would be CCI would be problematic, and these capacities for antibody detection and neutralization assays exist within the USG.

Ned

-----Original Message-----

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 9:27 PM
To: Lowy, Douglas (NIH/NCI) [E] [b6]; Santos, Michael (FNIH) [T] [b6]
Cc: Wholley, David (FNIH) [T] [b6]; Sharpless, Norman (NIH/NCI) [E] [b6]
Subject: FW: standardized immunology assays to facilitate and speed approval of a vaccine against Covid 19

In case this is of interest.

-----Original Message-----

From: Ed Scolnick [b6]
Sent: Thursday, May 14, 2020 8:58 PM
To: Marks, Peter (FDA/CBER) [b6]; Daniel Wattendorf [b6]; Emilio Emini [b6]; Fauci, Anthony (NIH/NIAID) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Tal Zaks [b6]
Cc: Lander [b6]; Deb Hung [b6]; Ramnik Xavier [b6]; Schreiber, Stuart [b6]; David R. Liu [b6]; Ben Cravatt [b6]; Michael Rosbash [b6]; Thomas Cantor [b6]; Michael Z Lin [b6]
Subject: standardized immunology assays to facilitate and speed approval of a vaccine against Covid 19

Hi to All: For the past few days, I have been working with Dr Deb Hung a Member of the Broad Institute. Deb has been a member for 15 years and is a pioneer in Infectious disease. As the memo indicates, she had developed 2 assays which will be invaluable for the current Corona Virus Vaccine effort and is almost finished developing a 3rd one as noted in this memo. Having these assays can potentially if trials go as planned lead to an approval of vaccines by the Fall. This would be analogous to Rapid approval of Cancer therapies. Additional studies would go on but early use of the Vaccine to stem the pandemic would be possible and would be a spectacular achievement for the Biomedical community.

The Broad is capable of running all the assays, sharing that data with the FDA which is supportive of the effort and keeping each company's data confidential from other companies. The Broad has proved that it can do high throughput assays in its genotyping, sequencing and PCR based work and can now extend this capability to the immune assays needed to help the National vaccine effort

We urge you to approve this effort rapidly. In the HIV effort when I was at Merck we organized a Company consortium of 12 companies to share phase 2 data without showing structures of antiviral compounds. That allowed 2 companies to begin combination therapy 5 years earlier than normal and led to the triple therapy regimens that changed the face of HIV from a death notice to a manageable disease. This proposal can do the same for this pandemic.

I have included Katharine Jansen on the "to" list but am sending it to her private email address.

COLL0000021963

I implore you to help activate this effort as fast as possible free from the usual bureaucratic barriers. The effort can help the companies and most importantly help human beings who are terrified of becoming infected and prevent a second wave of infections in the fall, an event which would decimate the public and the country.

You can reach me by email or by cell phone b6 I will make myself available and so will Deb Hung to answer your questions

Best wishes Edward Scolnick

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Sent: 5/15/2020 2:38:50 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
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Subject: RE: Time sensitive: Making your ACTIV Participation Public

Yes, I did hear from Rao, Lutz and Grobler. Below are folks who have not responded:

Ralph Baric, Ph.D.

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Professor, Department of Microbiology and Immunology
University of North Carolina, Gillings School of Global Public Health

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Sent: Friday, May 15, 2020 10:35 AM
To: Myles, Renate (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Have you hear back from others? How many people are missing now?

Sylva, Beth and Jonathan – how will we handle getting their permissions?

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Friday, May 15, 2020 10:33 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E]
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Thanks, Ashley and Lauren. Very helpful.

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Sent: Friday, May 15, 2020 7:53 AM

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Emilio Emini, Ph.D.
Director, TB & HIV Program
Bill & Melinda Gates Foundation

b6

Kathrin Jansen, Ph.D.
Senior Vice President and Head of Vaccine Research and Development
Pfizer

b6

Antonio Lanzavecchia, M.D.

Senior Vice President and Senior Research Fellow

Vir Biotechnology, Inc.

Director, Institute for Research in Biomedicine, Bellinzona, Switzerland

b6

Nancy Messonnier, M.D.

Director, Center for the National Center for Immunization and Respiratory Diseases

Centers for Disease Control and Prevention

b6

Jonathan Seals, Ph.D.

Director, Strategic Science and Technology

Biomedical Advanced Research and Development Authority

From: Collins, Francis (NIH/OD) [E]

b6

Sent: Thursday, May 14, 2020 11:00 AM

To: Collins, Francis (NIH/OD) [E]

b6

Cc: Myles, Renate (NIH/OD) [E]

Meltzer, Abbey (FNIH) [T]

b6

Wholley, David

(FNIH) [T] b6

Subject: Time sensitive: Making your ACTIV Participation Public

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.**

Thanks,
Francis

Francis S. Collins, MD, PhD
NIH Director

From: Menetski, Joseph (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 5/15/2020 2:57:39 PM
To: [b6] Tomas Cihlar [b6]
[b6]
[b6] Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai];
[b6]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
[b6] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras];
[b6] Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas /US [b6] Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]
CC: Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [b6] Hughes, Eric [b6]; Jansen, Kathrin [b6] Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Kim, Elizabeth [elkim@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Wachtel, Jonathan [jwachtel@deloitte.com]; Prabhavathi Fernandes [b6]; Diamond, Michael [b6] Rose Li [b6] Dana Carluccio [b6] Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];

Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [b6]; Dave Frankowski [b6]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; [b6] [b6]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]

Subject: RE: ACTIV Preclinical working group (Friday meeting)

Attachments: Therapeutic information request form-v7.docx

Dear Preclinical working group and invitees,

Part of our time today will be discussing the therapeutic information request form. I will be projecting this for discussion, but if you can't log on to zoom, here is the word doc. This is the current version that has additions from the clinical working group (thank you clinical working group!).

Looking forward to our discussion.

Joe

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T]

Sent: Tuesday, April 14, 2020 6:48 PM

To: [b6] Tomas Cihlar; [b6] Menetski, Joseph (FNIH) [T];

b6

[b6] Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; [b6] Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas /US; Anderson, James (NIH/OD) [E]; Qashu, Felicia (NIH/OD) [E]

Cc: Nancy Haigwood; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; [b6] Hild, Sheri (NIH/OD) [E]

Subject: ACTIV Preclinical working group (Friday meeting)

When: Friday, May 15, 2020 11:00 AM-12:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: [b6]

Holding time

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting

b6

Meeting ID:

b6

Password:

b6

One tap mobile

b6

US (New York)
US (Chicago)

Dial by your location

b6

US (New York)
US (Chicago)
US
US
US (Houston)
US (San Jose)
US (San Jose)

Meeting ID:

b6

Password:

b6

Find your local number:

b6

Sent: 5/15/2020 3:21:04 PM
To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]
CC: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

I'm on a call with Cheryl now and working group members are being added in real time – additions that come in today and over the weekend etc. will have to added on the next wave?

FNIH is forwarding Francis' email to Beth, Sylva, and Jonathan – they were not on her list.

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Friday, May 15, 2020 11:11 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Just heard from Judith Currier. Removed her from the list below. 19 more to go.

From: Myles, Renate (NIH/OD) [E]
Sent: Friday, May 15, 2020 10:39 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Yes, I did hear from Rao, Lutz and Grobler. Below are folks who have not responded:

Ralph Baric, Ph.D.

William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology
Professor, Department of Microbiology and Immunology
University of North Carolina, Gillings School of Global Public Health

Damon Deming, Ph.D.

Virologist, Division of Antiviral Products, Office of New Drugs
U.S. Food and Drug Administration

Greg Gatto, Ph.D.

Drug Development Regulatory Project Leader
RTI International

David Payne, Ph.D.

Vice President & Head, Medicine Opportunities Research Unit
GlaxoSmithKline

Louise Pitt, Ph.D.

Director, Center for Aerobiological Sciences
United States Army Medical Research Institute of Infectious Diseases

Jay Rappaport, Ph.D.

Professor of Microbiology and Immunology
Director and Chief Academic Officer
Tulane University National Primate Research Center

Frank Stegmeier, Ph.D.

Chief Scientific Officer
KSQ Therapeutics

Sylva Collins, Ph.D.

Director, Office of Biostatistics
U.S. Food and Drug Administration

John Farley, M.D., M.P.H.

Director, Office of Infectious Diseases
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

b6

Elliot Levy, M.D.

Senior Vice President, Global Development
Amgen

b6

Lionel Bascles, Ph.D.

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Carlos Garner, Ph.D.

Vice President, Global Regulatory Affairs
Eli Lilly and Company

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Director, Center for the National Center for Immunization and Respiratory Diseases

Centers for Disease Control and Prevention

b6

Jonathan Seals, Ph.D.

Director, Strategic Science and Technology

Biomedical Advanced Research and Development Authority

From: Parker, Ashley (NIH/OD) [E]

b6

Sent: Friday, May 15, 2020 10:35 AM

To: Myles, Renate (NIH/OD) [E]

b6

Cc: Brodd, Lauren (NIH/OD) [E]

Subject: RE: Time sensitive: Making your ACTIV Participation Public

Have you hear back from others? How many people are missing now?

Sylva, Beth and Jonathan – how will we handle getting their permissions?

From: Myles, Renate (NIH/OD) [E]

b6

Sent: Friday, May 15, 2020 10:33 AM

To: Parker, Ashley (NIH/OD) [E]

b6

Cc: Brodd, Lauren (NIH/OD) [E]

Subject: RE: Time sensitive: Making your ACTIV Participation Public

Thanks, Ashley and Lauren. Very helpful.

From: Parker, Ashley (NIH/OD) [E]

b6

Sent: Friday, May 15, 2020 10:27 AM

To: Myles, Renate (NIH/OD) [E]

b6

Cc: Brodd, Lauren (NIH/OD) [E]

Subject: RE: Time sensitive: Making your ACTIV Participation Public

Hi Renate,

Sparing FC's inbox and others.

With many thanks to Lauren for helping us with this. Please see edits attached and below – the alphabetizing of the names can be ignored as this is updated in the revised version you've provided.

A few minor edits:

- Co-chairs of the working groups should be identified
- Consistency with MD or M.D.
- Minor change to John Mellors

Thanks,
Ashley

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Friday, May 15, 2020 9:21 AM
To: Parker, Ashley (NIH/OD) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6]
Cc: Allen-Gifford, Patrice (NIH/OD) [E] [b6]; Wooldridge, Shannon (NIH/OD) [E] [b6]; Pollock, Rachel (NIH/OD) [E] [b6]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Hi Ashley:

Attached is the full list of members currently listed on the website in staging. I received the list from FNIH communications. Please let me know of any changes.

Thanks,
Renate

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Friday, May 15, 2020 9:11 AM
To: Myles, Renate (NIH/OD) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6]
Cc: Allen-Gifford, Patrice (NIH/OD) [E] [b6]; Wooldridge, Shannon (NIH/OD) [E] [b6]; Pollock, Rachel (NIH/OD) [E] [b6]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Hi Renate,

I've added the emails below but we have a major version control issues. I've been working with Cheryl to receive updates and did not have Sylvia Collins, Beth Bell and Jonathan Seals and apparently they are listed on a separate list the FNIH communications team is tracking.

We can send follow up emails to everyone except for those three – they will need to be contacted.

Moving forward, it may be best for you to receive updates from the communications team – FNIH is managing multiple spreadsheets one for the emails Cheryl is managing to schedule meetings and a separate list for the communications office.

Ralph Baric, Ph.D.

William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology
Professor, Department of Microbiology and Immunology
University of North Carolina, Gillings School of Global Public Health

[b6]

Damon Deming, Ph.D.

Virologist, Division of Antiviral Products, Office of New Drugs
U.S. Food and Drug Administration

[b6]

Greg Gatto, Ph.D.

Drug Development Regulatory Project Leader
RTI International

[b6]

Jay Grobler, Ph.D.

Director, Infectious Disease Biology
Merck & Co., Inc.

b6

Cat Lutz, Ph.D.

Senior Director, Mouse Repository & In Vivo Pharmacology, Rare and Orphan Disease Center
The Jackson Laboratory

b6

David Payne, Ph.D.

Vice President & Head, Medicine Opportunities Research Unit
GlaxoSmithKline

b6

b6

Director, Center for Aerobiological Sciences
United States Army Medical Research Institute of Infectious Diseases

b6

Srinivas Rao, DVM, Ph.D.

Global Head, Translational In Vivo Models Global Research Platform
Sanofi

b6

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b6

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Chief Scientific Officer
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Sylva Collins, Ph.D.

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U.S. Food and Drug Administration

b6

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Professor of Medicine
University of California Los Angeles
Division of Infectious Diseases
Chair, AIDS Clinical Trial Group (ACTG)

b6

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Centers for Disease Control and Prevention

b6

Jonathan Seals, Ph.D.

Director, Strategic Science and Technology
Biomedical Advanced Research and Development Authority

b6

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Friday, May 15, 2020 7:53 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Allen-Gifford, Patrice (NIH/OD) [E] [b6] Parker, Ashley (NIH/OD) [E]
[b6] Wooldridge, Shannon (NIH/OD) [E] [b6] Pollock, Rachel (NIH/OD)
[E] [b6]
Subject: FW: Time sensitive: Making your ACTIV Participation Public

Hi Francis:

Below is the list of 23 vpeople who have not yet responded to your email. I cross referenced these names with the email list that Ashely sent and pulled addresses from that list. I didn't find emails for a number of these people, but I know there was a second round that went out using emails I don't have. Hoping Ashley can provide the missing emails.

[b6]

Ralph Baric, Ph.D.

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Professor, Department of Microbiology and Immunology
University of North Carolina, Gillings School of Global Public Health

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Virologist, Division of Antiviral Products, Office of New Drugs
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b6

Jonathan Seals, Ph.D.

Director, Strategic Science and Technology
Biomedical Advanced Research and Development Authority

From: Collins, Francis (NIH/OD) [E]

b6

Sent: Thursday, May 14, 2020 11:00 AM

To: Collins, Francis (NIH/OD) [E]

b6

Cc: Myles, Renate (NIH/OD) [E]

Meltzer, Abbey (FNIH) [T]

b6

Wholley, David

(FNIH) [T]

b6

Subject: Time sensitive: Making your ACTIV Participation Public

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.**

Thanks,
Francis

Francis S. Collins, MD, PhD
NIH Director

From: Myles, Renate (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7D317F5626934585B3692A1823C1B522-MYLESR]
Sent: 5/15/2020 3:25:42 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Yes, definitely.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Friday, May 15, 2020 11:22 AM
To: Myles, Renate (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

I'm on a call with Cheryl now and working group members are being added in real time – additions that come in today and over the weekend etc. will have to added on the next wave?

FNIH is forwarding Francis' email to Beth, Sylva, and Jonathan – they were not on her list.

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Friday, May 15, 2020 11:11 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Just heard from Judith Currier. Removed her from the list below. 19 more to go.

From: Myles, Renate (NIH/OD) [E]
Sent: Friday, May 15, 2020 10:39 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Yes, I did hear from Rao, Lutz and Grobler. Below are folks who have not responded:

Ralph Baric, Ph.D.

William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology
Professor, Department of Microbiology and Immunology
University of North Carolina, Gillings School of Global Public Health

Damon Deming, Ph.D.

Virologist, Division of Antiviral Products, Office of New Drugs
U.S. Food and Drug Administration

Greg Gatto, Ph.D.

Drug Development Regulatory Project Leader
RTI International

David Payne, Ph.D.

Vice President & Head, Medicine Opportunities Research Unit
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Louise Pitt, Ph.D.

Director, Center for Aerobiological Sciences
United States Army Medical Research Institute of Infectious Diseases

Jay Rappaport, Ph.D.

Professor of Microbiology and Immunology
Director and Chief Academic Officer
Tulane University National Primate Research Center

Frank Stegmeier, Ph.D.

Chief Scientific Officer
KSQ Therapeutics

Sylva Collins, Ph.D.

Director, Office of Biostatistics
U.S. Food and Drug Administration

John Farley, M.D., M.P.H.

Director, Office of Infectious Diseases
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

b6

Elliot Levy, M.D.

Senior Vice President, Global Development
Amgen

b6

Lionel Bascles, Ph.D.

Senior Vice President, Global Head of Clinical Sciences & Operations
Sanofi

b6

Carlos Garner, Ph.D.

Vice President, Global Regulatory Affairs
Eli Lilly and Company

b6

Peter Stein, M.D.

Director of Office of New Drugs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

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Director, TB & HIV Program
Bill & Melinda Gates Foundation

b6

Kathrin Jansen, Ph.D.
Senior Vice President and Head of Vaccine Research and Development
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b6

Antonio Lanzavecchia, M.D.
Senior Vice President and Senior Research Fellow
Vir Biotechnology, Inc.
Director, Institute for Research in Biomedicine, Bellinzona, Switzerland

b6

Nancy Messonnier, M.D.
Director, Center for the National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention

b6

Jonathan Seals, Ph.D.
Director, Strategic Science and Technology
Biomedical Advanced Research and Development Authority

From: Parker, Ashley (NIH/OD) [E] b6
Sent: Friday, May 15, 2020 10:35 AM
To: Myles, Renate (NIH/OD) [E] b6
Cc: Brodd, Lauren (NIH/OD) [E]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Have you hear back from others? How many people are missing now?

Sylva, Beth and Jonathan – how will we handle getting their permissions?

From: Myles, Renate (NIH/OD) [E] b6
Sent: Friday, May 15, 2020 10:33 AM
To: Parker, Ashley (NIH/OD) [E] b6
Cc: Brodd, Lauren (NIH/OD) [E]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Thanks, Ashley and Lauren. Very helpful.

From: Parker, Ashley (NIH/OD) [E] b6
Sent: Friday, May 15, 2020 10:27 AM
To: Myles, Renate (NIH/OD) [E] b6
Cc: Brodd, Lauren (NIH/OD) [E]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Hi Renate,

Sparing FC's inbox and others.

With many thanks to Lauren for helping us with this. Please see edits attached and below – the alphabetizing of the names can be ignored as this is updated in the revised version you've provided.

A few minor edits:

- Co-chairs of the working groups should be identified
- Consistency with MD or M.D.
- Minor change to John Mellors

Thanks,
Ashley

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Friday, May 15, 2020 9:21 AM
To: Parker, Ashley (NIH/OD) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6]
Cc: Allen-Gifford, Patrice (NIH/OD) [E] [b6]; Wooldridge, Shannon (NIH/OD) [E] [b6]; Pollock, Rachel (NIH/OD) [E] [b6]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Hi Ashley:

Attached is the full list of members currently listed on the website in staging. I received the list from FNIH communications. Please let me know of any changes.

Thanks,
Renate

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Friday, May 15, 2020 9:11 AM
To: Myles, Renate (NIH/OD) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6]
Cc: Allen-Gifford, Patrice (NIH/OD) [E] [b6]; Wooldridge, Shannon (NIH/OD) [E] [b6]; Pollock, Rachel (NIH/OD) [E] [b6]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Hi Renate,

I've added the emails below but we have a major version control issues. I've been working with Cheryl to receive updates and did not have Sylvia Collins, Beth Bell and Jonathan Seals and apparently they are listed on a separate list the FNIH communications team is tracking.

We can send follow up emails to everyone except for those three – they will need to be contacted.

Moving forward, it may be best for you to receive updates from the communications team – FNIH is managing multiple spreadsheets one for the emails Cheryl is managing to schedule meetings and a separate list for the communications office.

Ralph Baric, Ph.D.

William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology
Professor, Department of Microbiology and Immunology
University of North Carolina, Gillings School of Global Public Health

[b6]

Damon Deming, Ph.D.

Virologist, Division of Antiviral Products, Office of New Drugs
U.S. Food and Drug Administration

b6

Greg Gatto, Ph.D.

Drug Development Regulatory Project Leader
RTI International

b6

Jay Grobler, Ph.D.

Director, Infectious Disease Biology
Merck & Co., Inc.

b6

Cat Lutz, Ph.D.

Senior Director, Mouse Repository & In Vivo Pharmacology, Rare and Orphan Disease Center
The Jackson Laboratory

b6

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GlaxoSmithKline

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Louise Pitt, Ph.D.

Director, Center for Aerobiological Sciences
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b6

Srinivas Rao, DVM, Ph.D.

Global Head, Translational In Vivo Models Global Research Platform
Sanofi

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Frank Stegmeier, Ph.D.

Chief Scientific Officer
KSQ Therapeutics

b6

Sylva Collins, Ph.D.

Director, Office of Biostatistics
U.S. Food and Drug Administration

b6

Judith Currier, M.D.

Professor of Medicine

University of California Los Angeles
Division of Infectious Diseases
Chair, AIDS Clinical Trial Group (ACTG)

b6

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Director, Office of Infectious Diseases
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

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Centers for Disease Control and Prevention

b6

Jonathan Seals, Ph.D.

Director, Strategic Science and Technology
Biomedical Advanced Research and Development Authority

b6

From: Myles, Renate (NIH/OD) [E]

b6

Sent: Friday, May 15, 2020 7:53 AM

To: Collins, Francis (NIH/OD) [E]

b6

Cc: Allen-Gifford, Patrice (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]

b6

[E]; Wooldridge, Shannon (NIH/OD) [E]; Pollock, Rachel (NIH/OD)
[E]

b6

b6

b6

Subject: FW: Time sensitive: Making your ACTIV Participation Public

Hi Francis:

Below is the list of 23 vpeople who have not yet responded to your email. I cross referenced these names with the email list that Ashely sent and pulled addresses from that list. I didn't find emails for a number of these people, but I know there was a second round that went out using emails I don't have. Hoping Ashley can provide the missing emails.

b6

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Professor, Department of Microbiology and Immunology
University of North Carolina, Gillings School of Global Public Health

Damon Deming, Ph.D.

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Centers for Disease Control and Prevention

b6

Jonathan Seals, Ph.D.

Director, Strategic Science and Technology
Biomedical Advanced Research and Development Authority

From: Collins, Francis (NIH/OD) [E]

b6

Sent: Thursday, May 14, 2020 11:00 AM

To: Collins, Francis (NIH/OD) [E]

b6

Cc: Myles, Renate (NIH/OD) [E] < > Meltzer, Abbey (FNIH) [T] < > Wholley, David (FNIH) [T]

b6

b6

Subject: Time sensitive: Making your ACTIV Participation Public

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.**

Thanks,
Francis

Francis S. Collins, MD, PhD
NIH Director

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/15/2020 4:54:29 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [b6] Keith Gottesdiener [b6] Eric Hughes [b6] LaVange, Lisa M [b6] Elliott Levy [b6] Sandeep Menon [b6] Amanda Peppercorn [b6] Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [b6] Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [b6] Wung, Peter /US [b6] Karen Lynn Price Pamela Tenaerts, M.D. [b6] Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Burgess, Timothy [b6] Beumont-Mauviel, Maria [JRDUS] [b6] Peeters, Monika [JRDBE] [b6] Woodfall, Brian [JRDUS] [b6] Van Heeswijk, Rolf [JRDBE] [b6]
CC: Mary Biggs [b6] Demarcus [b6] Macone, Erin [b6] Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [b6] Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #17
Attachments: ACTIV Therapeutics-Clinical_MP Subgroup_15May2020 Meeting Guide.pdf
Location: [b6]
Start: 5/15/2020 5:00:00 PM
End: 5/15/2020 6:00:00 PM
Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butters; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Patterson, Amy (NIH/NHLBI) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Burgess, Timothy; Beumont-Mauviel, Maria [JRDUS]; Peeters, Monika [JRDBE]; Woodfall, Brian [JRDUS]; Van Heeswijk, Rolf [JRDBE]

Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]

Stacey Adam is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting

b6

Meeting ID: **b6**

Password: **b6**

One tap mobile

b6 US (Chicago)
US (New York)

Dial by your location

b6 US (Chicago)
US (New York)
US (Germantown)
US (Houston)
US (San Jose)
US (San Jose)
US (Tacoma)

Meeting ID: **b6**

Password: **b6**

Find your local number: **b6**

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/15/2020 5:18:14 PM
To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]
CC: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

We will need to ask Rachel. If you did not see it go out, I would assume not since you were on the cc line, right?

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Friday, May 15, 2020 1:14 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Did ExecSec send another message this morning?

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Friday, May 15, 2020 1:10 PM
To: Myles, Renate (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Cheryl sent a message to Beth, Sylva, and Jonathan giving them until 2pm today.

I think we can reply to FC emails he sent yesterday, adding those non responders to the bcc line letting them know we are following up if they can let us know by 3pm today or ASAP unless you think this should come from FC directly.

We would need to remove the 3 names listed above.

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Friday, May 15, 2020 1:01 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

We can push the website live whenever we're ready, but we would have to remove the list of folks below. How should we proceed? Should I ask Francis?

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Friday, May 15, 2020 11:22 AM
To: Myles, Renate (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

I'm on a call with Cheryl now and working group members are being added in real time – additions that come in today and over the weekend etc. will have to added on the next wave?

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Sent: Friday, May 15, 2020 11:11 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Just heard from Judith Currier. Removed her from the list below. 19 more to go.

From: Myles, Renate (NIH/OD) [E]
Sent: Friday, May 15, 2020 10:39 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Yes, I did hear from Rao, Lutz and Grobler. Below are folks who have not responded:

Ralph Baric, Ph.D.

William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology
Professor, Department of Microbiology and Immunology
University of North Carolina, Gillings School of Global Public Health

Damon Deming, Ph.D.

Virologist, Division of Antiviral Products, Office of New Drugs
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Director, Center for Aerobiological Sciences
United States Army Medical Research Institute of Infectious Diseases

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Professor of Microbiology and Immunology
Director and Chief Academic Officer
Tulane University National Primate Research Center

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Sanofi

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Biomedical Advanced Research and Development Authority

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Sent: Friday, May 15, 2020 10:35 AM
To: Myles, Renate (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Have you hear back from others? How many people are missing now?

Sylva, Beth and Jonathan – how will we handle getting their permissions?

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Friday, May 15, 2020 10:33 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Thanks, Ashley and Lauren. Very helpful.

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Sent: Friday, May 15, 2020 10:27 AM
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- Consistency with MD or M.D.
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Thanks,
Ashley

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Friday, May 15, 2020 9:21 AM
To: Parker, Ashley (NIH/OD) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6]
Cc: Allen-Gifford, Patrice (NIH/OD) [E] [b6]; Wooldridge, Shannon (NIH/OD) [E]
[b6]; Pollock, Rachel (NIH/OD) [E] [b6]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Hi Ashley:

Attached is the full list of members currently listed on the website in staging. I received the list from FNIH communications. Please let me know of any changes.

Thanks,
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From: Myles, Renate (NIH/OD) [E]

b6

Sent: Friday, May 15, 2020 7:53 AM

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b6

Cc: Allen-Gifford, Patrice (NIH/OD) [E]

b6

Parker, Ashley (NIH/OD) [E]

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Wooldridge, Shannon (NIH/OD) [E]

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Pollock, Rachel (NIH/OD)

[E] b6

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From: Collins, Francis (NIH/OD) [E] b6

Sent: Thursday, May 14, 2020 11:00 AM

To: Collins, Francis (NIH/OD) [E] b6

Cc: Myles, Renate (NIH/OD) [E] b6 Meltzer, Abbey (FNIH) [T] b6; Wholley, David (FNIH) [T] b6

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Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.**

Thanks,
Francis

Francis S. Collins, MD, PhD
NIH Director

From: Pollock, Rachel (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4887CB3513E242DFA7D2DF712DCC6D6A-POLLOCKRC]
Sent: 5/15/2020 5:37:36 PM
To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]
CC: Allen-Gifford, Patrice (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=67262490d6d441b48efec1aff0700250-allengiffor]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wooldridge, Shannon (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=385b0c281f104789873e956dc91b7c06-burdense]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Renate – I do not see anything in FC's sent box, but perhaps it went out from someone else? Ashley may be able to confirm/offer more information.

Rachel Pollock

O: [b6]
C: [b6]

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Friday, May 15, 2020 1:19 PM
To: Pollock, Rachel (NIH/OD) [E] [b6]
Cc: Allen-Gifford, Patrice (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Wooldridge, Shannon (NIH/OD) [E] [b6]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Hi Rachel:

Did another email go out this morning to the non-responders?

From: Myles, Renate (NIH/OD) [E]
Sent: Friday, May 15, 2020 8:13 AM
To: Pollock, Rachel (NIH/OD) [E] [b6]
Cc: Allen-Gifford, Patrice (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Wooldridge, Shannon (NIH/OD) [E] [b6]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Thanks, Rachel. Jay Grobler just responded, so I've removed him from the list. Will you be sending it out this morning?

From: Pollock, Rachel (NIH/OD) [E] [b6]
Sent: Friday, May 15, 2020 8:08 AM
To: Myles, Renate (NIH/OD) [E] [b6]
Cc: Allen-Gifford, Patrice (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Wooldridge, Shannon (NIH/OD) [E] [b6]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Renate – in case it is helpful, attached is what I believe to be the send round email, and which includes the full list of email addresses in the bcc line. CC'ing Ashley to confirm.

Rachel Pollock

O: [b6]
C: [b6]

From: Myles, Renate (NIH/OD) [E] [b6]

Sent: Friday, May 15, 2020 7:53 AM

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Subject: RE: Time sensitive: Making your ACTIV Participation Public
Attachments: RE: Time sensitive: Making your ACTIV Participation Public

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Hi Ashley:

Do you have the emails for those missing emails? I can reply all to the original email and ask again.

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To: Myles, Renate (NIH/OD) [E]

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Have you hear back from others? How many people are missing now?

Sylva, Beth and Jonathan – how will we handle getting their permissions?

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Subject: FW: Time sensitive: Making your ACTIV Participation Public

Hi Francis:

Below is the list of 23 vpeople who have not yet responded to your email. I cross referenced these names with the email list that Ashely sent and pulled addresses from that list. I didn't find emails for a number of these people, but I know there was a second round that went out using emails I don't have. Hoping Ashley can provide the missing emails.

b6

Ralph Baric, Ph.D.

William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology
Professor, Department of Microbiology and Immunology
University of North Carolina, Gillings School of Global Public Health

Damon Deming, Ph.D.

Virologist, Division of Antiviral Products, Office of New Drugs
U.S. Food and Drug Administration

Greg Gatto, Ph.D.

Drug Development Regulatory Project Leader
RTI International

Jay Grobler, Ph.D.

Director, Infectious Disease Biology
Merck & Co., Inc.

Cat Lutz, Ph.D.

Senior Director, Mouse Repository & In Vivo Pharmacology, Rare and Orphan Disease Center
The Jackson Laboratory

David Payne, Ph.D.

Vice President & Head, Medicine Opportunities Research Unit
GlaxoSmithKline

Louise Pitt, Ph.D.

Director, Center for Aerobiological Sciences
United States Army Medical Research Institute of Infectious Diseases

Srinivas Rao, DVM, Ph.D.

Global Head, Translational In Vivo Models Global Research Platform
Sanofi

Jay Rappaport, Ph.D.

Professor of Microbiology and Immunology
Director and Chief Academic Officer
Tulane University National Primate Research Center

Frank Stegmeier, Ph.D.

Chief Scientific Officer
KSQ Therapeutics

Sylva Collins, Ph.D.

Director, Office of Biostatistics
U.S. Food and Drug Administration

Judith Currier, M.D.

Professor of Medicine
University of California Los Angeles
Division of Infectious Diseases
Chair, AIDS Clinical Trial Group (ACTG)

b6

John Farley, M.D., M.P.H.

Director, Office of Infectious Diseases
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

b6

Elliot Levy, M.D.

Senior Vice President, Global Development
Amgen

b6

Lionel Bascles, Ph.D.

Senior Vice President, Global Head of Clinical Sciences & Operations
Sanofi

b6

Carlos Garner, Ph.D.

Vice President, Global Regulatory Affairs
Eli Lilly and Company

b6

Peter Stein, M.D.

Director of Office of New Drugs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

b6

Beth Bell, M.D., MPH

Clinical Professor, Global Health
University of Washington

Emilio Emini, Ph.D.

Director, TB & HIV Program
Bill & Melinda Gates Foundation

b6

Kathrin Jansen, Ph.D.

Senior Vice President and Head of Vaccine Research and Development
Pfizer

b6

Antonio Lanzavecchia, M.D.

Senior Vice President and Senior Research Fellow
Vir Biotechnology, Inc.
Director, Institute for Research in Biomedicine, Bellinzona, Switzerland

b6

Nancy Messonnier, M.D.

Director, Center for the National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention

b6

Jonathan Seals, Ph.D.

Director, Strategic Science and Technology

Biomedical Advanced Research and Development Authority

From: Collins, Francis (NIH/OD) [E] [b6]

Sent: Thursday, May 14, 2020 11:00 AM

To: Collins, Francis (NIH/OD) [E] [b6]

Cc: Myles, Renate (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]

Subject: Time sensitive: Making your ACTIV Participation Public

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.**

Thanks,
Francis

Francis S. Collins, MD, PhD
NIH Director

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/15/2020 7:18:50 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Judy Currier [b6]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Sandeep Menon [b6]; Proschan, Michael (NIH/NIAID) [E]; [b6]; Read, Sarah (NIH/NIAID) [E]; [b6]; Price, Dionne (FDA/CDER); [b6]; Rubin, Daniel B. (FDA/CDER); [b6]; Farley, John (FDA/CDER); [b6]; Karen Lynn Price; [b6]; Eron, Joe [b6]; Javan, Arzhang (NIH/NIAID) [E]; [b6]; Roa, Jhoanna [b6]; Kim, Peter (NIH/NIAID) [E]; [b6]
CC: Demarcus [b6]; Tountas, Karen (FNIH) [T]; [b6]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jhoanna Roa [b6]; Eron, Joseph J Jr [b6]; Smith, David; Paul Klekotka [b6]; Ajay Nirula [b6]
Subject: ACTIV TX-Clinical Master Protocol Outpatient mAbs Writing Team Meeting #1
Attachments: a5401-d03-activ-051620.docx
Location: [b6]
Start: 5/18/2020 5:00:00 PM
End: 5/18/2020 6:00:00 PM
Show Time As: Busy

Required Attendees: Judy Currier; Eric Hughes; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; [b6]; [b6]; Eron, Joe; Javan, Arzhang (NIH/NIAID) [E]; Roa, Jhoanna; [b6]; Kim, Peter (NIH/NIAID) [E]
Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Jhoanna Roa; Eron, Joseph J Jr; Smith, David; Paul Klekotka

Updated with New Protocol Version

Dear ACTIV-2 Master Protocol Writing Team,

Thank you all for being willing to get together so quickly. I look forward to the ACTIV and the ACTG teams working together to make this protocol great and get it going quickly.

We will work to get a full list of participants and their roles together for this meeting to distribute. In the meantime, the ACTG team has been kind enough to send the current draft of their protocol for us to start from. They have noted to me that they have removed some agent specific information for confidentiality purposes, but all else should be ready for this group to review and start thinking and commenting on.

Thanks,

Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/15/2020 7:21:08 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Colli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [b6]; Keith Gottesdiener [b6]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Elliott Levy [b6]; Sandeep Menon [b6]; Amanda Peppercorn [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [b6]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [b6]; Wung, Peter /US [b6]; Karen Lynn Price [b6]; Pamela Tenaerts, M.D. [b6]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Burgess, Timothy [b6]; Beumont-Mauviel, Maria [JRDUS] [b6]; Peeters, Monika [JRDBE] [b6]; Woodfall, Brian [JRDUS] [b6]; Van Heeswijk, Rolf [JRDBE] [b6]
CC: Mary Biggs [b6]; Demarcus [b6]; Macone, Erin [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [b6]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #19
Location: [b6]
Start: 5/20/2020 5:00:00 PM
End: 5/20/2020 6:00:00 PM
Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butters; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Patterson, Amy (NIH/NHLBI) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Burgess, Timothy; Beumont-Mauviel, Maria [JRDUS]; Peeters, Monika [JRDBE]; Woodfall, Brian [JRDUS]; Van Heeswijk, Rolf [JRDBE]

Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/15/2020 7:21:09 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [b6]; Keith Gottesdiener [b6]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Elliott Levy [b6]; Sandeep Menon [b6]; Amanda Peppercorn [b6]; Proschan, Michael (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [b6]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [b6]; Wung, Peter /US [b6]; Karen Lynn Price [b6]; Pamela Tenaerts, M.D. [b6]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Higgs, Elizabeth (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Burgess, Timothy [b6]; Beumont-Mauviel, Maria [JRDUS] [b6]; Peeters, Monika [JRDBE] [b6]; Woodfall, Brian [JRDUS] [b6]; Van Heeswijk, Rolf [JRDBE] [b6]
CC: Mary Biggs [b6]; Demarcus [b6]; Macone, Erin [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [b6]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #19
Location: [b6]
Start: 5/20/2020 5:00:00 PM
End: 5/20/2020 6:00:00 PM

- Required Attendees:

Bozzette, Sam (NIH/NCATS) [E]; Joan Butters; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Patterson, Amy (NIH/NHLBI) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Burgess, Timothy; Beumont-Mauviel, Maria [JRDUS]; Peeters, Monika [JRDBE]; Woodfall, Brian [JRDUS]; Van Heeswijk, Rolf [JRDBE]
- Optional Attendees:

Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/15/2020 7:21:09 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [b6]; Butterton, Joan [b6]; Judy Currier [b6]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Karen Lynn Price [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6]; Woodcock, Janet (FDA/CDER) [b6]; Stein, Peter (FDA/CDER) [b6]; Carlos O Garner [b6]; Bugin, Kevin (FDA/CDER) [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]
CC: Demarcus [b6]; Tountas, Karen (FNIH) [T] [b6]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]

Subject: ACTIV TX-Clinical Master Protocol mAbs Steering Committee - ACTIV2 Synopsis Review

Attachments: 5401 Protocol Synopsis 051920v3.docx

Location: [b6]

Start: 5/20/2020 5:00:00 PM

End: 5/20/2020 6:00:00 PM

Show Time As: Busy

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Judy Currier; Eric Hughes; Lisa LaVange; Read, Sarah (NIH/NIAID) [E]; Karen Lynn Price; Higgs, Elizabeth (NIH/NIAID) [E]; Woodcock, Janet (FDA/CDER); Stein, Peter (FDA/CDER); Carlos O Garner; Bugin, Kevin (FDA/CDER); Marks, Gilbert (OS/ASPR/BARDA) (CTR)
Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]

Dear ACTIV TX-Clinical Master Protocol mAbs Steering Committee,

Please find attached the synopsis of the outpatient protocol for review at our meeting today. This was assembled by the ACTG group based on our writing team conversations and then edited a bit by Lisa and Karen for the statistical sections.

This document is NOT ready to share beyond this group yet, but could be gotten ready in short turn if needed for the company summit, Janet. We will just need to know when that is.

Finally, we will be discussing the selection of the inpatient network for the companion protocol today.

Thanks,

Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/15/2020 7:21:21 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Colli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [b6]; Keith Gottesdiener [b6]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Elliott Levy [b6]; Sandeep Menon [b6]; Amanda Peppercorn [b6]; Proschan, Michael (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [b6]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [b6]; Wung, Peter /US [b6]; Karen Lynn Price [b6]; Pamela Tenaerts, M.D. [b6]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Higgs, Elizabeth (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Burgess, Timothy [b6]; Beumont-Mauviel, Maria [JRDUS] [b6]; Peeters, Monika [JRDBE] [b6]; Woodfall, Brian [JRDUS] [b6]; Van Heeswijk, Rolf [JRDBE] [b6]
CC: Mary Biggs [b6]; Demarcus [b6]; Macone, Erin [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [b6]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #20
Location: [b6]
Start: 5/22/2020 6:00:00 PM
End: 5/22/2020 7:00:00 PM
Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butters; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Patterson, Amy (NIH/NHLBI) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Burgess, Timothy; Beumont-Mauviel, Maria [JRDUS]; Peeters, Monika [JRDUS]; Woodfall, Brian [JRDUS]; Van Heeswijk, Rolf [JRDUS]

Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/15/2020 7:21:22 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [b6]; Keith Gottesdiener [b6]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Elliott Levy [b6]; Sandeep Menon [b6]; Amanda Peppercorn [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [b6]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Vincent, Michael [b6]; Wung, Peter /US [b6]; Karen Lynn Price [b6]; Pamela Tenaerts, M.D. [b6]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Burgess, Timothy [b6]; Beumont-Mauviel, Maria [JRDUS] [b6]; Peeters, Monika [JRDBE] [b6]; Woodfall, Brian [JRDUS] [b6]; Van Heeswijk, Rolf [JRDBE] [b6]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Bharucha_David [b6]; Gavin, Brian [b6]; Sadeh, Jonathan [b6]; Harler, Mary Beth [b6]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Mary Biggs [b6]; Demarcus [b6]; Macone, Erin [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [b6]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Melsheimer, Rich [CNTNL] [b6]
Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #20

Attachments: ACTIV_Therapeutics Clinical Master Protocol Sub Group_22May2020 Meeting Guide.pdf; Agenda capture 1.PNG

Location: b6

Start: 5/22/2020 6:00:00 PM

End: 5/22/2020 6:30:00 PM

Show Time As: Busy

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Patterson, Amy (NIH/NHLBI) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Burgess, Timothy; Beumont-Mauviel, Maria [JRDUS]; Peeters, Monika [JRDBE]; Woodfall, Brian [JRDUS]; Van Heeswijk, Rolf [JRDBE]; Brown, Jeremy (NIH/NINDS) [E]; Bharucha_David; Gavin, Brian; Sadeh, Jonathan; Harler, Mary Beth

Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Melsheimer, Rich [CNTNL]

Dear ACTIV TX-Clinical Master Protocol Subgroup,

For this meeting today, we have decide to split this meeting into two meetings to make most efficient use of everyone's time. This first 30 minute meeting will be the entire group with the companies for ACTIV-1 to discuss the next steps for this protocol. The second 30 minutes will now become a meeting of the mAb Steering Committee to finalize some decisions for the ACTIV-2 protocol that need to be completed by EOD today.

Thanks for your understanding.

Please find attached the slides for this first meeting today.

Thanks, Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/15/2020 7:24:01 PM
To: Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [b6]; Keith Gottesdiener [b6]; Elliott Levy [b6]; Wung, Peter /US [b6]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [b6]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bafd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]

Subject: ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #11

Location: [b6]

Start: 5/19/2020 5:00:00 PM

End: 5/19/2020 6:00:00 PM

Show Time As: Tentative

Required Attendees: Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E]

Optional Attendees: Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; [b6]; Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E]; [b6]

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/15/2020 7:24:02 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Ruxandra Draghia-Akli [b6]; Mellors, John W [b6]; Naimish Patel [b6]; Colvis, Christine (NIH/NCATS) [E] [b6]; Young, John [b6]; Stein, Peter (FDA/CDER) [b6]; Poole, Mike [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [b6]; Vincent, Michael [b6]; Keith Gottesdiener [b6]; Elliott Levy [b6]; Wung, Peter /US [b6]; Koroshetz, Walter (NIH/NINDS) [E] [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6]; Carlos O Garner [b6]; Goff, David (NIH/NHLBI) [E] [b6]
CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [b6]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [b6]; Ward, Jackie (NIH/NINDS) [E] [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; [b6]
Subject: ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #11
Attachments: Therapeutic information request form-v9-clean.docx; ACTIV_Therapeutics Clinical Agent Prioritization Sub Group_19May2020 Meeting Guide.pdf
Location: [b6]
Start: 5/19/2020 5:00:00 PM
End: 5/19/2020 6:00:00 PM
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Required Attendees: Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E]
Optional Attendees: Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; [b6]; Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] [b6]; Rose Li Central Account

Dear ACTIV TX-Clinical Agent Prioritization Subgroup,

Please find attached the materials for tomorrow's call.

1. Slides with topics and agenda internal.
2. Updated Company RFI/Survey for final review.

Thanks,
Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
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To: Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [b6]; Keith Gottesdiener [b6]; Elliott Levy [b6]; Wung, Peter /US [b6]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [b6]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #12
Location: [b6]
Start: 5/21/2020 3:00:00 PM
End: 5/21/2020 4:00:00 PM
Show Time As: Tentative

Required Attendees: Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E]
Optional Attendees: Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; [b6]; Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] [b6]

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/15/2020 7:24:08 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Ruxandra Draghia-Akli [b6]; Mellors, John W [b6]; Naimish Patel [b6]; Colvis, Christine (NIH/NCATS) [E] [b6]; Young, John [b6]; Stein, Peter (FDA/CDER) [b6]; Poole, Mike [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [b6]; Vincent, Michael [b6]; Keith Gottesdiener [b6]; Elliott Levy [b6]; Wung, Peter /US [b6]; Koroshetz, Walter (NIH/NINDS) [E] [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6]; Carlos O Garner [b6]; Goff, David (NIH/NHLBI) [E] [b6]
CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [b6]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [b6]; Ward, Jackie (NIH/NINDS) [E] [b6]; Rose Li Central Account [FNIH@roseliassociates.com]
Subject: ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #12
Attachments: 2020-05-19_TX-Clinical_WG_Agent_Prioritization_Committee_Meeting-Summary.pdf; ACTIV_Therapeutics Clinical Agent Prioritization Sub Group_21May2020 Meeting Guide.pdf
Location: [b6]
Start: 5/21/2020 3:00:00 PM
End: 5/21/2020 4:00:00 PM
Show Time As: Busy

Required Attendees: Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E]
Optional Attendees: Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; [b6]; Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] [b6]; Rose Li Central Account

Dear TX-Clinical Agent Prioritization Subgroup,

Please find attached the formal summary from yesterday's meeting.

In addition, please find the slides for tomorrow's meetings. Please let me know if you have any amendments or additions.

Thanks,
Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/15/2020 7:27:04 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [b6]; Eisner, Mark [b6]; Gottesdiener, Keith [b6]; Hughes, Eric [b6]; Judy Carrier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [elkim@deloitte.com]; LaVange, Lisa [b6]; Levy, Elliot [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaa06ebd70-parkeras]; Patel, Naimish [b6]; Peppercorn, Amanda [b6]; Poole, Mike [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coll]; Amanda Peppercorn [b6]; Garner, Carl [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Burgess, Timothy [b6]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]
CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [b6]; Jansen, Kathrin [b6]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [b6]; Biggs, Mary [b6]; Butcher, Tina [b6]; Demarcus [b6]; Macone, Erin [b6]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetiskijp]; James, Stephanie (FNIH)
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan
 [jwachtel@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Alvarez, Rosa [rosalvarez@deloitte.com];
 Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [b6]; Rose
 Li Central Account [FNIH@roseliassociates.com]; Anderson, Margaret [marganderson@deloitte.com]; Lucas
 Smalldon [b6]; Stratton, Benjamin [bstratton@DELOITTE.com];
 [b6]; Mollica, Linda /US [b6]; Qashu, Felicia (NIH/OD) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Goff, David (NIH/NHLBI) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Rubin, Daniel B. (FDA/CDER)
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]

Subject: ACTIV TX-Clinical Working Group Meeting #7

Location: [b6]

Start: 5/21/2020 6:00:00 PM

End: 5/21/2020 7:00:00 PM

Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Butterton, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proshan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]

Optional Attendees: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; [b6]; Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; [b6]; Rubin, Daniel B.

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/15/2020 7:27:06 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [b6]; Eisner, Mark [b6]; Gottesdiener, Keith [b6]; Hughes, Eric [b6]; Judy Carrier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [elkim@deloitte.com]; LaVange, Lisa [b6]; Levy, Elliot [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaafe06ebd70-parkeras]; Patel, Naimish [b6]; Peppercorn, Amanda [b6]; Poole, Mike [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coll]; Amanda Peppercorn [b6]; Garner, Carl [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Burgess, Timothy [b6]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-roosenbey]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [b6]; Jansen, Kathrin [b6]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [b6]; Biggs, Mary [b6]; Butcher, Tina [b6]; Demarcus [b6]; Macone, Erin [b6]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan [jwachtel@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Alvarez, Rosa [rosalvarez@deloitte.com]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [b6] Rose Li Central Account [FNIH@roseliassociates.com]; Anderson, Margaret [marganderson@deloitte.com]; Lucas Smalldon [b6]; Stratton, Benjamin [bstratton@DELOITTE.com]; [b6] Mollica, Linda /US [b6]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]

Subject: ACTIV TX-Clinical Working Group Meeting #7
Attachments: ACTIV Therapeutics-Clinical Full Working Group 21May2020 Meeting Guide.pdf
Location: [b6]

Start: 5/21/2020 6:00:00 PM
End: 5/21/2020 7:00:00 PM
Show Time As: Busy

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]

Optional Attendees: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; [b6] Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] [b6]; Rubin, Daniel B. (FDA/CDER)

Dear ACTIV TX-Clinical WG,

Looking forward to seeing you all soon at the meeting. Please find attached the slides for the meeting.

Thanks,
Stacey

Join Zoom Meeting

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/16/2020 2:58:42 AM
To: Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [b6]; Keith Gottesdiener [b6]; Elliott Levy [b6]; Wung, Peter /US [b6]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [b6]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bafd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Dana Carluccio [b6]; Rose Li Central Account [FNIH@roseliassociates.com]
Subject: Second Follow-up from ACTIV TX-Clinical Agent Prioritization Subgroup #10
Attachments: 2020-05-14_TX-Clinical_WG_Agent_Prioritization_Committee_Meeting Summary.pdf; Therapeutic information request form-v8.docx

Dear ACTIV TX-Clinical Agent Prioritization Subgroup,

Please find attached the formal summary from the call yesterday.

In addition, I am attaching the most current version of the RFI/Survey. Reminder if you have any suggestions please email me. We could particularly use help on the neutralizing mAbs section.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

APAR0000005399

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/16/2020 3:34:48 AM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [b6]; Eisner, Mark [b6]; Gottesdiener, Keith [b6]; Hughes, Eric [b6]; Judy Carrier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [elkim@deloitte.com]; LaVange, Lisa [b6]; Levy, Elliot [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [b6]; Peppercorn, Amanda [b6]; Poole, Mike [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coll]; Amanda Peppercorn [b6]; Garner, Carl [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Burgess, Timothy [b6]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]
CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [b6]; Jansen, Kathrin [b6]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [b6]; Biggs, Mary [b6]; Butcher, Tina [b6]; Demarcus [b6]; Macone, Erin [b6]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH)
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan
 [jwachtel@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Alvarez, Rosa [rosalvarez@deloitte.com];
 Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [b6]; Rose
 Li Central Account [FNIH@roseliassociates.com]; Anderson, Margaret [marganderson@deloitte.com]; Lucas
 Smalldon [b6]; Stratton, Benjamin [bstratton@DELOITTE.com];
 [b6] Mollica, Linda /US [b6]; Qashu, Felicia (NIH/OD) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Goff, David (NIH/NHLBI) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Rubin, Daniel B. (FDA/CDER)
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]

Subject: Follow-up from ACTIV TX-Clinical Working Group #6
Attachments: 2020-05-14_TX-Clinical_WG_Meeting_Summary.pdf

Dear TX-Clinical Working Group,

Please find attached the formal summary of our meeting yesterday. Don't hesitate to contact me if you have additional or amendments that need to be made.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] | Mobile: [b6]

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 5/16/2020 2:34:05 PM
To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]
CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Allen-Gifford, Patrice (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=67262490d6d441b48efec1aff0700250-allengiffor]; Pollock, Rachel (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4887cb3513e242dfa7d2df712dcc6d6a-pollockrc]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Didn't get to this last night. Any change in the plan now?
Francis

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Friday, May 15, 2020 3:53 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]; Allen-Gifford, Patrice (NIH/OD) [E] [b6]
[b6]; Pollock, Rachel (NIH/OD) [E] [b6]; Burklow, John (NIH/OD) [E] [b6]
[b6]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

That's fine. We still haven't pushed the page live. We can do it Monday morning, which gives people time over the weekend to respond. We'll remove the names of the people who do not respond by Monday morning.

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Friday, May 15, 2020 3:51 PM
To: Myles, Renate (NIH/OD) [E] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]; Allen-Gifford, Patrice (NIH/OD) [E] [b6]
[b6]; Pollock, Rachel (NIH/OD) [E] [b6]; Burklow, John (NIH/OD) [E] [b6]
[b6]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

I will do, but can't get to it until 4:30

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Friday, May 15, 2020 3:48 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]; Allen-Gifford, Patrice (NIH/OD) [E] [b6]
[b6]; Pollock, Rachel (NIH/OD) [E] [b6]; Burklow, John (NIH/OD) [E] [b6]
[b6]
Subject: FW: Time sensitive: Making your ACTIV Participation Public

Hi Francis:

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me to do it for you. They'd probably pay more attention if it came from you though. Your original email is at the bottom of this string.

Thanks,
Renate

b6

Ralph Baric, Ph.D.

William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology
Professor, Department of Microbiology and Immunology
University of North Carolina, Gillings School of Global Public Health

b6

Damon Deming, Ph.D.

Virologist, Division of Antiviral Products, Office of New Drugs
U.S. Food and Drug Administration

b6

Jay Grobler, Ph.D.

Director, Infectious Disease Biology
Merck & Co., Inc.

b6

David Payne, Ph.D.

Vice President & Head, Medicine Opportunities Research Unit
GlaxoSmithKline

b6

Louise Pitt, Ph.D.

Director, Center for Aerobiological Sciences
United States Army Medical Research Institute of Infectious Diseases

b6

Srinivas Rao, DVM, Ph.D.

Global Head, Translational In Vivo Models Global Research Platform
Sanofi

b6

Jay Rappaport, Ph.D.

Professor of Microbiology and Immunology
Director and Chief Academic Officer
Tulane University National Primate Research Center

b6

Frank Stegmeier, Ph.D.

Chief Scientific Officer

KSQ Therapeutics

b6

Judith Currier, M.D.

Professor of Medicine

University of California Los Angeles

Division of Infectious Diseases

Chair, AIDS Clinical Trial Group (ACTG)

b6

John Farley, M.D., M.P.H.

Director, Office of Infectious Diseases

Center for Drug Evaluation and Research

U.S. Food and Drug Administration

b6

Elliot Levy, M.D.

Senior Vice President, Global Development

Amgen

b6

Lionel Bascles, Ph.D.

Senior Vice President, Global Head of Clinical Sciences & Operations

Sanofi

b6

Carlos Garner, Ph.D.

Vice President, Global Regulatory Affairs

Eli Lilly and Company

b6

Peter Stein, M.D.

Director of Office of New Drugs

Center for Drug Evaluation and Research

U.S. Food and Drug Administration

b6

Emilio Emini, Ph.D.

Director, TB & HIV Program

Bill & Melinda Gates Foundation

b6

Kathrin Jansen, Ph.D.

Senior Vice President and Head of Vaccine Research and Development

Pfizer

b6

Antonio Lanzavecchia, M.D.

Senior Vice President and Senior Research Fellow

Vir Biotechnology, Inc.

Director, Institute for Research in Biomedicine, Bellinzona, Switzerland

b6

Nancy Messonnier, M.D.

Director, Center for the National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention

b6

From: Collins, Francis (NIH/OD) [E] b6

Sent: Thursday, May 14, 2020 11:00 AM

To: Collins, Francis (NIH/OD) [E]

b6

Cc: Myles, Renate (NIH/OD) [E] b6 Meltzer, Abbey (FNIH) [T] b6 Wholley, David (FNIH) [T] b6

Subject: Time sensitive: Making your ACTIV Participation Public

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.**

Thanks,
Francis

Francis S. Collins, MD, PhD
NIH Director

APAR0000002854

From: Myles, Renate (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7D317F5626934585B3692A1823C1B522-MYLESR]
Sent: 5/16/2020 2:42:20 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Allen-Gifford, Patrice (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=67262490d6d441b48efec1aff0700250-allengiffor]; Pollock, Rachel (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4887cb3513e242dfa7d2df712dcc6d6a-pollockrc]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]
Subject: Re: Time sensitive: Making your ACTIV Participation Public

I removed four people who have since responded both from the list and the email addresses. The remaining 14 non-responders are listed below.

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Friday, May 15, 2020 3:48 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]; Allen-Gifford, Patrice (NIH/OD) [E] [b6]
[b6]; Pollock, Rachel (NIH/OD) [E] [b6]; Burklow, John (NIH/OD) [E]
[b6]
Subject: FW: Time sensitive: Making your ACTIV Participation Public

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Director of Office of New Drugs
Center for Drug Evaluation and Research
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Senior Vice President and Senior Research Fellow

Vir Biotechnology, Inc.

Director, Institute for Research in Biomedicine, Bellinzona, Switzerland

b6

Nancy Messonnier, M.D.

Director, Center for the National Center for Immunization and Respiratory Diseases

Centers for Disease Control and Prevention

b6

From: Collins, Francis (NIH/OD) [E] b6

Sent: Thursday, May 14, 2020 11:00 AM

To: Collins, Francis (NIH/OD) [E] b6

Cc: Myles, Renate (NIH/OD) [E] b6 Meltzer, Abbey (FNIH) [T] b6; Wholley, David (FNIH) [T] b6

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Thanks,
Francis

Francis S. Collins, MD, PhD
NIH Director

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/16/2020 8:32:27 PM
To: Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [b6] LaVange, Lisa M [b6] Sandeep Menon [b6] Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price [b6] Eron, Joe [b6] Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; [b6]
CC: Demarcus [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: ACTIV TX-Clinical Master Protocol Outpatient mAbs Writing Team Meeting #1
Attachments: a5401-d02-051620_hold.docx
Location: [b6]
Start: 5/18/2020 5:00:00 PM
End: 5/18/2020 6:00:00 PM
Show Time As: Tentative

Required Attendees: Judy Currier; Eric Hughes; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; [b6] Eron, Joe; Javan, Arzhang (NIH/NIAID) [E]; Roa, Jhoanna; [b6]
Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]

Dear ACTIV-2 Master Protocol Writing Team,

Thank you all for being willing to get together so quickly. I look forward to the ACTIV and the ACTG teams working together to make this protocol great and get it going quickly.

We will work to get a full list of participants and their roles together for this meeting to distribute. In the meantime, the ACTG team has been kind enough to send the current draft of their protocol for us to start from. They have noted to me that they have removed some agent specific information for confidentiality purposes, but all else should be ready for this group to review and start thinking and commenting on.

Thanks,

Stacey

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Meeting ID:

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US (San Jose)
US (San Jose)
US (Tacoma)
US (Houston)

Meeting ID:

b6

Password:

b6

Find your local number:

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/16/2020 8:33:35 PM
To: Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Sandeep Menon [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price [b6]; Eron, Joe [b6]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; [b6]
CC: Demarcus [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: ACTIV TX-Clinical Master Protocol Outpatient mAbs Writing Team Meeting #1
Attachments: a5401-d02-051620_hold.docx

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Thanks,

Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [b6] Mobile: [b6]

Join Zoom Meeting

[b6]

APAR0000005393-2443715

Meeting ID:

b6

Password:

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US (New York)

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US (New York)
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US (San Jose)
US (San Jose)
US (Tacoma)
US (Houston)

Meeting ID:

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Password:

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/16/2020 8:37:37 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [b6]; Keith Gottesdiener [b6]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Elliott Levy [b6]; Sandeep Menon [b6]; Amanda Peppercorn [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [b6]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [b6]; Wung, Peter /US [b6]; Karen Lynn Price [b6]; Pamela Tenaerts, M.D. [b6]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Burgess, Timothy [b6]; Beumont-Mauviel, Maria [JRDU] [b6]; Peeters, Monika [JRDBE] [b6]; Woodfall, Brian [JRDU] [b6]; Van Heeswijk, Rolf [JRDBE] [b6]
CC: Mary Biggs [b6]; Demarcus [b6]; Macone, Erin [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [b6]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Note about ACTIV TX-Clinical Master Protocol Subgroup Meeting #19

Dear ACTIV TX-Clinical Master Protocol Subgroup,

Similarly to my last note, many of you will see this meeting disappear from your calendar as well. We will be repurposing this for another discussion with the SARS-CoV-2 neutralizing mAbs subteam.

Thank you for your understanding and we look forward to updating you all on our progress on Thursday and Friday.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Foundation for the National Institutes of Health

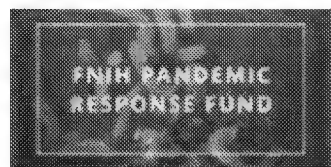
Direct: [b6] Mobile: [b6]

fnih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/16/2020 8:42:31 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Karen Lynn Price [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Carlos O Garner [b6]
CC: Demarcus [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]

Subject: ACTIV TX-Clinical Master Protocol mAbs Steering Committee - ACTIV2 Synopsis Review
Location: [b6]

Start: 5/20/2020 5:00:00 PM
End: 5/20/2020 6:00:00 PM
Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Judy Currier; Eric Hughes; Lisa LaVange; Read, Sarah (NIH/NIAID) [E]; Karen Lynn Price; Higgs, Elizabeth (NIH/NIAID) [E]; Woodcock, Janet (FDA/CDER); Stein, Peter (FDA/CDER); Carlos O Garner
Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]

Dear ACTIV TX-Clinical Master Protocol mAbs Steering Committee,

As noted in our meeting today, this will be the call for us to review the Synopsis of the SARS-CoV-2 neutralizing mAb outpatient master protocol.

Thanks,

Stacey

Join Zoom Meeting

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/16/2020 9:58:35 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Coll]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [b6]; Keith Gottesdiener [b6]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Elliott Levy [b6]; Sandeep Menon [b6]; Amanda Peppercorn [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [b6]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [b6]; Wung, Peter /US [b6]; Karen Lynn Price Pamela Tenaerts, M.D. [b6]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Burgess, Timothy [b6]; Beumont-Mauviel, Maria [JRDUS] [b6]; Peeters, Monika [JRDBE] [b6]; Woodfall, Brian [JRDUS] [b6]; Van Heeswijk, Rolf [JRDBE]
CC: Mary Biggs [b6]; Demarcus [b6]; Macone, Erin [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [b6]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Follow-up to ACTIV TX-Clinical Master Protocol Subgroup Meeting #17
Attachments: ACTIV_Therapeutics-Clinical_MP Sub-Group Meeting 15May2020_Key Takeaways.pdf

Dear ACTIV TX-Clinical Master Protocol Subgroup,

Please find attached the action items and summary notes for yesterday's meeting. Please let us know if you have any additions or amendments.

APAR0000005389

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Foundation for the National Institutes of Health

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Sent: 5/16/2020 11:58:56 PM
To: Marks, Peter [b6]; Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: ChAdOx1

Just a brief word of concern – let's be sure we don't come down too strong on [b4] role in the recent vaccine WG discussions, which expressed a perspective that probably needed to be heard. We don't want to put [b4] in a position that might lead to their decision to pull out of ACTIV. Better to draw them in more closely.

From: Marks, Peter [b6]
Sent: Saturday, May 16, 2020 3:13 PM
To: Fauci, Anthony (NIH/NIAID) [E] [b6]; Mascola, John (NIH/VRC) [E] [b6]
Collins, Francis (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]
Cc: Wholley, David (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: ChAdOx1

Dear Tony,

Will certainly include you next week on this call.

Best Regards,
Peter

From: Fauci, Anthony (NIH/NIAID) [E] [b6]
Sent: Thursday, May 14, 2020 9:12 AM
To: Marks, Peter [b6]; Mascola, John R (NIH) [b6]; Collins, Francis S (NIH) [b6]
Lane, Henry C (NIH) [b6]
Cc: Wholley, David N (NIH) [b6]; Tabak, Lawrence A (NIH) [b6]; Parker, Ashley S (NIH) [b6]
Subject: RE: ChAdOx1

I would also like to be on that call with the [b4] CEO if we could possible arrange it.

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases
Building 31, Room 7A-03
31 Center Drive, MSC 2520
National Institutes of Health

COLL0000009584-2443304

Bethesda, MD 20892-2520

Phone: [b6]

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From: Marks, Peter [b6]

Sent: Thursday, May 14, 2020 9:05 AM

To: Mascola, John (NIH/VRC) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]

Cc: Fauci, Anthony (NIH/NIAID) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]

Subject: RE: ChAdOx1

Dear John,

Thanks for bringing the [b4] issue up. I think that a call with their head of development and possibly also their CEO may be needed, and I wonder if Francis would like to join?

Best Regards,
Peter

From: Mascola, John (NIH/VRC) [E] [b6]

Sent: Thursday, May 14, 2020 9:03 AM

To: Marks, Peter [b6]; Collins, Francis S (NIH) [b6]; Lane, Henry C (NIH) [b6]

Cc: Fauci, Anthony S (NIH) [b6]; Wholley, David N (NIH) [b6]; Tabak, Lawrence A (NIH) [b6]; Parker, Ashley S (NIH) [b6]

Subject: RE: ChAdOx1

Francis - we did make good progress on ACTIV Vaccine WG. Yesterday on the vaccine clinical trials subgroup, we presented the harmonized protocol approach and high level details of phase 3 design. There was good input on both and general agreement, with some useful recommendations on efficient ways to conduct phase 3.

One issues is that [b4]
[b4]
[b4] When we asked for suggestions for DSMB, Kathrin said she did not agree that we should ask for nominations – because this issue required more discussion [b4]
[b4] Doug Lowy was on the call, so may be useful to get his perspective.

John

From: Marks, Peter [b6]

Sent: Thursday, May 14, 2020 6:23 AM

To: Collins, Francis (NIH/OD) [E] [b6]; Mascola, John (NIH/VRC) [E] [b6]; Lane,

COLL0000009584-2443304

Cliff (NIH/NIAID) [E] [b6]
Cc: Fauci, Anthony (NIH/NIAID) [E] [b6]; Wholley, David (FNIH) [T] [b6] Tabak,
Lawrence (NIH/OD) [E] [b6] Parker, Ashley (NIH/OD) [E] [b6]>
Subject: RE: ChAdOx1

Dear Francis,

We had made good progress with the Oxford AZ team on the clinical end before the contracting period began. From my last conversation with the AZ clinical team they were on board with the USG concept of a large phase 3 trial, potentially as part of a master protocol if the timing was right. Their major issue was getting moving rapidly.

Among other things, Tony, John and I discussed the concept that in addition to harmonized protocols we would consider merging the first two vaccines that are currently aiming to start phase 3 into one master protocol if they appeared to be staying on schedule for a July 1 start. Planning on one DSMB for at least these two candidates therefore makes a lot of sense.

Later today I will be speaking with John again about this merged concept. After giving it very careful consideration, though it certainly involves significant extra work in protocol development and logistic planning, I believe that we should be actively planning for the two contingencies simultaneously:

- 1) Moderna and Oxford AZ enter phase 3 at different times (more than 2 weeks apart), in which case we will go with harmonized protocols, non-overlapping sites, and a single DSMB, and
- 2) Moderna and Oxford AZ enter phase 3 simultaneously (less than 2 weeks apart), in which case we should plan on one master protocol making use of all available sites. There is much to recommend this option, such that it is worth the effort in planning even if circumstances preclude proceeding along this path: 1) it could reduce the overall size of the trials by 10,000; 2) could help drive enrollment since fewer people will receive placebo; and 3) it will produce comparative efficacy data.

[b4]
[b4] that will have to be addressed, but these do not appear to be showstoppers. Happy to discuss further.

Best Regards,
Peter

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 5:38 AM
To: Mascola, John R (NIH) [b6]; Lane, Henry C (NIH) [b6]; Marks, Peter [b6]
Cc: Fauci, Anthony S (NIH) <afauci@niaid.nih.gov>; Wholley, David N (NIH) <dwholley@fnih.org>; Tabak, Lawrence A (NIH) <lawrence.tabak@nih.gov>; Parker, Ashley S (NIH) <ashley.parker@nih.gov>
Subject: ChAdOx1

Gentlemen:

I need to know the update on where we are with Oxford, A-Z, and ChAdOx1. I see there's a BARDA WebEx at 5 pm, and I have a rescheduled phone call this morning with John Bell. I'd like to be as useful as possible in making a plan that includes this vaccine program as part of the harmonized master protocol. Advice about how to use the call with John Bell most effectively would be most welcome!

And did the Vaccines WG make good progress yesterday on the details of the harmonized master protocol? Did they agree in principle to a single DSMB?

Thanks, Francis

Sent: 5/17/2020 1:30:43 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
CC: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]
BCC: Annunziato, Paula [b6]; Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbf6108d53148f684dad333fce983de-aarvin.stan]; Buchbinder, Susan [b6]; Corey, Larry [b6]; Davis, Mark [b6]; Emini, Emilio [b6]; Hanon, Emmanuel [emmanuel.hanon@gsk.com]; Haynes, Barton [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d4a05845b5b4069ad0447fb60ebfa79-hayne002.mc]; Hotez, Peter [b6]; Jansen, Kathrin [b6]; Lanzavecchia, Antonio [b6]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda]; Mascola, John [b6]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Offit, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cdb9cc56fde4598a57b423d484dcf9f-offit.email]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Santos, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f34e73d1185b4c5383df3b73c87aa455-Nancy.santo]; Schuitemaker, Hanneke [b6]; Tartaglia, Jim [b6]; Tolman, Brett [btolman@deloitte.com]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bascles, Lionel [b6]; Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [b6]; Desrosiers, Betsy [b6]; Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshov, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshovj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Heaton, Penny [b6]; Kurilla, Mike [b6]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Payton, Manzine [b6]; Resnansky, Laura [b6]; Srinivasan, Badhri [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

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[b6]; Wachtel, Jonathan [jwachtel@deloitte.com]; Woodcock, Janet (FDA/CDER)
[/o=ExchangeLabs/ou=Exchange Administrative Group
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(OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group
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[rosalvarez@deloitte.com]; Anderson, Annaliesa [b6]; Baric, Ralph
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[b6]; Colvis, Christine [b6]; Deming, Damon (FDA/CDER)
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[b6]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[b6]; Ottinger, Liz [b6]; Parker, Ashley (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Payne, David
[b6]; Rao, Srinivas [b6]; Rappaport, Jay [b6]
Stegmeier, Frank [b6]; Young, John [b6]; Adam, Stacey (FNIH) [T]
[b6]; Bozzette, Sam (NIH/NCATS) [E] [b6]; Buchman, Tim (OS/ASPR/BARDA)
(CTR) [b6]; Butterton, Joan [b6]; Currier, Judy
[b6]; De Claro, R. Angelo (FDA/CDER) [b6]; Draghia-Akli,
Ruxandra [b6]; Eisner, Mark [b6]; Gottesdiener, Keith
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[b6]; Santos, Michael (FNIH) [T] [b6]; Shen, Yuan Li (FDA/CDER)
[b6]; Stein, Peter (FDA/CDER) [b6]

Subject: ACTIV Comprehensive News Clips

Attachments: ACTIV_NewsClips_4.18.2020.docx

Dear ACTIV Working Group Members,

Please see the comprehensive news clips on ACTIV provided by the NIH Office of Communications and Public Liaison.

Comprehensive News Clips of the ACTIV Public-Private Partnership

NIH Launches Effort To Speed Up Development Of COVID-19 Treatments

NPR

April 17, 2020

By Mary Louise Kelly

Heard on All Things Considered

In an bid to help speed up the development of potential treatment options and a vaccine for COVID-19, the National Institutes of Health on Friday announced a new public-private research partnership.

The new initiative will be spearheaded by the NIH but also include the Food and Drug Administration, other parts of the federal government and a list of 16 companies that includes some of the biggest players in the pharmaceutical industry. Among the companies participating in the effort are Pfizer, Johnson & Johnson and Merck.

"We need to have all hands on deck from every sector to speed up the process of identifying those treatments that are going to work and to get the vaccines also developed, tested, to make sure they're safe and effective in the maximum possible speed," said Dr. Francis Collins, director of the NIH, in an interview with NPR's *All Things Considered*.

The announcement comes after President Trump and public health officials on Thursday unveiled new guidelines for states to begin reopening the country. Health experts say that in order to safely do that, there needs to be more testing, contact tracing and better drugs to treat COVID-19. Ultimately, for things to truly return to normal, an effective vaccine is needed.

Collins said there are already two vaccines in phase one trials, and behind that, a series of more than 40 other vaccines being developed as well. But he cautioned that the public should expect failures along the way.

"Somewhere in there may be a winner, even if most of them are losers," he said.

Collins also provided an update on testing of antiviral drug, remdesivir, and shared his thoughts on Dr. Anthony Fauci, the high-profile director of the National Institute of Allergy and Infectious Diseases.

Here are excerpts from the conversation.

There's a lot of buzz about an antiviral called remdesivir.

Remdesivir is certainly, I think, at the top of most people's hopeful list, but not yet proven. Just to report, yesterday although not yet peer reviewed, that in a monkey model it looked as if this did provide benefit for COVID-19. ... We're running a human trial with now 800 participants enrolled more quickly than expected. We will know, I think, in the next two to four weeks whether it worked or not.

[A] question about one of the most prominent faces of U.S. anti-virus efforts, Dr. Anthony Fauci ... Have you come under any pressure to fire him?

Absolutely not. He is a wonderful public servant, an amazingly smart infectious disease expert. He and I have a nightly phone call every evening to catch up on what's happened with his life down at the White House and mine trying to manage the NIH. He's the best ally I could ever have.

Listen to the full interview on All Things Considered at the audio link above.

Drug Industry Coordinates Covid-19 Response With NIH

Bloomberg Law

April 17, 2020

By Jeannie Baumann

- AbbVie, Eli Lilly, Merck among more than dozen drug companies involved
- Aims to coordinate biomedical research response globally

More than a dozen drug companies including Pfizer Inc., Johnson & Johnson, and Sanofi are coordinating their Covid-19 efforts with the NIH to push out new treatments and vaccines.

The public-private partnership plans to develop an international framework for prioritizing vaccine and drug candidates, streamlining clinical trials, coordinating regulatory processes across different countries, and using assets available among all collaborators to respond rapidly to both the current and future pandemics. The National Institutes of Health announced the Accelerating COVID-19 Therapeutic Interventions and Vaccines partnership Friday.

More than 300 clinical trials on Covid-19 are underway, and that number increases almost daily, a spokesperson for the Pharmaceutical Research and Manufacturers of America told Bloomberg Law earlier this week. But more than 90% of drug candidates fail in the clinical trial stage, and there are concerns about manufacturers' ability to scale up production to treat a worldwide pandemic once a vaccine or therapeutic becomes available.

NIH Director Francis S. Collins said the partnership aims to break down traditional boundaries in the biomedical research ecosystem to identify and prioritize the most promising therapies for clinical trials.

"Because we all know this particular virus is going to be with us for some time, the best hope we have as we think to limit the number of ill people and deaths from this disease is to develop and test rigorously therapeutic interventions that may save lives," Collins said Friday at a press briefing.

Clinical Trials

There are already about 100 ideas that have been put forward for clinical therapeutics, Collins said. He said that by June or July he expects to have some data showing which of the promising compounds to treat Covid-19 are working and should be prioritized in drug development.

There are also more than 40 vaccine candidates that are now in clinical trials, Collins said.

Esther Krofah, executive director at FasterCures, said Friday at a separate policy event hosted by the Commonwealth Fund that there are about 86 active vaccine projects and that she expects two dozen more to enter clinical trials by the end of the summer or early fall. Faster Cures, which is part of the think tank the Milken Institute, is tracking the development of potential Covid-19 medicines and vaccines.

The Food and Drug Administration has been “very open to creative ideas,” about rapidly moving forward with a vaccine once it’s proven safe and effective, Collins said.

Flexibility in how scientists set up their clinical trials and using real-world evidence can help speed up the process, Peter Marks, director of the FDA’s Center for Biologics Evaluation and Research, said at the Commonwealth Fund event.

“We can’t dismiss out of hand any potential useful design here—real-world evidence base, traditional base, or otherwise,” Marks said.

Marks didn’t rule out the possibility of issuing an emergency authorization for a vaccine, but he said it would depend on the evidence and if the virus is still circulating at that point.

Collaboration Needed

The NIH is leading the partnership with the nonprofit Foundation for the NIH, the Health and Human Services Office of the Assistant Secretary for Preparedness and Response, the Centers for Disease Control and Prevention, the FDA, and the European Medicines Agency.

The chief scientific officers of Pfizer and Johnson & Johnson both said in statements that ending the pandemic is beyond the ability of any single entity.

“COVID-19 is the most significant global health challenge of our lifetime, and it will take all of us working together as a global community to put an end to this pandemic,” Paul Stoffels, chief scientific officer at Johnson & Johnson, said.

Other companies involved in the effort are AbbVie Inc., Amgen Inc., AstraZeneca plc, Bristol Myers Squibb, Evotec, GlaxoSmithKline plc, KSQ Therapeutics Inc., Eli Lilly and Co., Merck & Co. Inc., Roche Holding AG, Takeda Pharmaceutical Co. Ltd., and Vir Biotechnology.

Gilead, whose antiviral product remdesivir has been described as the most advanced stage of development, wasn’t among the companies listed in the NIH announcement.

Future Implications

The work of the partnership could boost the ability of drug companies and the NIH to respond to future pandemics, Collins said.

ACTIV’s work could serve as a roadmap for public-private partnerships to identify and prioritize experimental compounds and to develop more creative approaches to creating new tools and standards for evaluating medical products.

“I don’t think anybody involved in this standing back and looking at it would say this is really just a one-shot deal, even though we’re focused on it right now for the urgency of the moment,” Collins said.

—With assistance from Jacquie Lee

To tame testing chaos, NIH and firms join forces to streamline coronavirus vaccine and drug efforts

Science

April 17, 2020

By Jocelyn Kaiser

More than 100 treatments and vaccines are in development to stem the COVID-19 pandemic, and some onlookers have worried that this sprawling and potentially duplicative effort is wasting time and resources. Hoping to bring order to the chaos, the National Institutes of Health (NIH) and major drug companies today announced a plan to stage carefully designed clinical trials of the drugs and vaccines they have decided are the highest priorities for testing and development.

The public-private partnership involves NIH, other U.S. government agencies, 16 pharma companies and biotechs, and the nonprofit Foundation for the National Institutes of Health (FNIH). It aims to develop "an international strategy" for COVID-19 research, a press release states. However, NIH Director Francis Collins told reporters during a press call today that, "It is primarily a U.S. focused effort."

The initiative, called Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV), aims to make efficient use of NIH funding and its clinical trial networks by working with companies to evaluate data on early candidates, selecting those that have the most promise and are not already part of rigorous human tests.

NIH is stepping in partly because of concerns that some potential treatments, such as hydroxychloroquine/chloroquine, are being touted by some researchers as effective based on poorly designed trials. "We need the best research standards," says former NIH director and Sanofi executive Elias Zerhouni, who sits on FNIH's board. "To me, the whole effort is to create a synergy between all of the players."

Collins said NIH began discussions with companies just 1 month ago, and plans gelled at a 3 April meeting. There was "unanimous agreement that the time has come to put aside any of the obstacles ... [to] such a public-private partnership and bring all the full resources and ideas together in a variety of ways that neither sector could do alone," Collins said.

Joining forces

ACTIV is partly modeled on a long-established FNIH-organized program called the Accelerating Medicines Partnership, in which companies join forces with NIH to generate shared data, such as biomarkers in Alzheimer's disease. Its goals include giving companies access to animal models and drug screening programs in high-security biosafety labs, as well as developing a "master protocol" and setting clinical standards for assessing a drug's efficacy that would be shared across trials. Companies will also share data on immune responses to candidate vaccines. Although focused on the United States, NIH says ACTIV is also working with the European Medicines Agency.

NIH is assembling working groups of scientists who will inventory drugs and vaccines at different stages of development, and then decide which are most promising for future testing and not already in well-designed studies. In making that list, the experts will also consider which untested compounds can most quickly move into human trials, and which could be manufactured in large quantities. The top-rated compounds will get priority for the \$1.8 billion Congress gave NIH for COVID-19 research as part of pandemic recovery bills, and preferred access to NIH's dozen or more clinical trial networks.

Collins noted that once ACTIV has started coordinating clinical trials, it might become easier to rapidly start, end, or redesign trials to focus on the most promising candidates. As an example, he noted that NIH easily recruited 800 patients, 300 more than needed, to test the drug remdesivir (results are expected soon). If an additional candidate compound was available, he noted, NIH could have offered those 300 patients the option of becoming involved in a different trial instead.

NIH and its partners say they have put off, for now, deciding how to answer potentially thorny questions about intellectual property (IP) ownership and the pricing of any new treatments developed under the partnership. That's a reasonable strategy given the urgency, says science policy specialist Robert Cook-Deegan of Arizona State University, Tempe. "It's pretty clear that they're aware the IP could get complicated," he says. And he doubts that pricing issues "will play out the way it usually does, with companies pricing to maximize and government passively going along," if only because there is likely to be intense public scrutiny of the effort.

Collins pointed out that companies are unlikely to be motivated by profits after seeing their own clinical trial efforts shut down by COVID-19. Executives are "desperate" to get their businesses running again and "therefore willing to do whatever it takes both altruistically and practically," he predicted.

Growing efforts to coordinate

The NIH project joins numerous other COVID-19 research coordination efforts around the world. In the United Kingdom, for example, a trial testing several drugs called RECOVERY is being led by the University of Oxford and tapping nearly 1000 patients at 132 hospitals run by the country's National Health Service. Although the U.S. effort has been slower than some others to get started, "no doubt when the NIH gets going, it will be a ... very efficient study," says Mene Pangalos, executive vice president of bioPharmaceuticals R&D at AstraZeneca. "Hopefully, they won't do the same molecules they

are doing in the U.K., and between us all, we'll learn faster." NIH says its working groups include representatives from efforts such as RECOVERY to avoid such duplication.

One global health leader is noticeably absent from the list of ACTIV's partners: the World Health Organization (WHO). It, too, has been coordinating COVID-19 research, organizing a set of global drug trials called SOLIDARITY.

WHO chief scientist Soumya Swaminathan said her agency welcomes the NIH effort. But for vaccines, she contends that WHO is well-positioned to coordinate the field with an expert group that's now being formed. "The best and most efficient way would be to consider one large global study which would look at different vaccine candidates," she says.

Collins says NIH is keeping tabs on WHO's efforts as it makes its own plan. And infectious disease expert Daniel Bausch of the London School of Hygiene & Tropical Medicine says WHO does not have the capacity to launch the effort NIH has in mind. "It will be important, however, to have NIH and WHO coordination, especially to ensure equitable participation in the conduct of the trials and access to the products that they might produce," Bausch says.

Richard Danzig, former secretary of the U.S. Navy who is heavily involved in international vaccine planning, says that while "the NIH effort is commendable," it doesn't directly take on another challenge once a vaccine has been developed: how to make enough to vaccinate the world's population. "We need also," Danzig says, "to prepare global manufacturing for vaccine production."

With reporting by Jon Cohen and David Malakoff.

U.S., European health agencies to partner drugmakers in coronavirus fight

Reuters

April 17, 2020

By Saumya Sibi Joseph

U.S. health agencies, the European drug regulator and 16 top drugmakers will collaborate on vaccine and drug development efforts to fight the coronavirus pandemic, the U.S. National Institutes of Health said on Friday.

The partnership, known as the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV), will focus on coordinating regulatory decisions and provide funding to move promising therapies into human trials.

"We need to bring the full power of the biomedical research enterprise to bear on this crisis," NIH Director Dr. Francis Collins said in a statement bit.ly/34HYTfk.

The participants include the U.S. Food and Drug Administration, the European Medicines Agency and drugmakers Pfizer Inc, Johnson & Johnson and GlaxoSmithKline Plc.

There are currently no approved treatments or vaccines for the coronavirus, which has infected 2.14 million globally, according to a Reuters tally.

There are over 100 potential vaccine and therapeutic candidates for COVID-19, the respiratory illness caused by the novel coronavirus, and the partnership aims to help prioritize development and connect clinical trial networks to test new and repurposed candidates quickly and efficiently.

Azar announces new effort to streamline COVID-19 research

NBC News

April 17, 2020

By Sara G. Miller

The National Institutes of Health is launching a public-private partnership aimed at developing a national strategy to coordinate COVID-19 drug and vaccine research.

Research for coronavirus therapies and vaccines across the country has been scattered and disconnected, in a number of unrelated clinical trials. The new initiative, called "Accelerating COVID-19 Therapeutic Interventions and Vaccines," or ACTIV, aims to coordinate and streamline these efforts.

"The ACTIV partnership will bring new levels of coordination and speed to public and private work on therapies and vaccines for COVID-19," HHS Sec. Alex Azar said in a statement Friday. "By bringing together 16 pharmaceutical

companies and five government agencies here and abroad, the ACTIV partnership will accelerate the amazing work being done every day by scientists and innovators inside and outside of government."

The government agencies include HHS's Biomedical Advanced Research and Development Authority, the Centers for Disease Control and Prevention, the Food and Drug Administration, and abroad, the European Medicines Agency.

NIH partners with 16 drug companies in hopes of accelerating Covid-19 treatments and vaccines

STAT

April 17, 2020

By Lev Facher

The National Institutes of Health on Friday announced it would launch a sweeping public-private partnership between federal researchers and 16 pharmaceutical companies, aimed at coordinating and accelerating the development of Covid-19 treatments and vaccines.

The partnership, to be known as Accelerating Covid-19 Therapeutic Interventions and Vaccines, or ACTIV, is meant to standardize research between the federally funded researchers and a broad array of drug companies, and prioritize research into drugs and vaccines that are having high near-term potential.

"Now is the time to come together with unassailable objectivity to swiftly advance the development of the most promising vaccine and therapeutic candidates that can help end the COVID-19 global pandemic," Francis Collins, the NIH director, said in a statement.

The new collaboration will focus on standardizing the methods and models that researchers are using to test promising Covid-19 compounds. It will also provide researchers access to high-level laboratory facilities and standardize endpoints to ensure different companies and researchers are judging potential medicines by the same criteria. Finally, it would establish one joint control arm to be shared among all clinical trials, the NIH said in a press release.

The partnership will establish a system to precisely coordinate clinical trials to make sure all trials have adequate capacity and can tailor their populations to "different populations and disease stages."

It will also create a steering committee to effectively determine which drugs should be prioritized for further research and which drugs should be deprioritized — effectively, to cull the group of over 100 potential treatments and vaccines, keeping only the most promising.

The announcement comes as drug companies and government researchers around the world scramble to develop cures and vaccines to fight the Covid-19 pandemic, which has killed roughly 145,000 people worldwide and 33,000 in the U.S. alone.

NIH, the federal government's roughly \$39 biomedical research agency, has already played a prominent role. Tony Fauci, who leads the National Institute of Allergy and Infectious Diseases — an institute within NIH — has emerged as a key adviser within the Trump administration's coronavirus response.

The National Heart, Lung, and Blood Institute, another institute within NIH, last week launched research projects measuring the efficacy of hydroxychloroquine, the antimalarial drug that President Trump has touted as a promising coronavirus treatment. Last week, NIAID and a trio of other institutes announced a separate study aimed at measuring the true rate of coronavirus infection in the U.S. by measuring the number of adults who have coronavirus antibodies but have not displayed symptoms.

Trump made his first visit to the NIH's campus last month.

HHS launches public-private partnership to develop vaccines, therapies to treat coronavirus

FOX News

April 17, 2020

By Brooke Singman

The Department of Health and Human Services on Friday announced plans to launch a new public-private partnership to develop a national strategy to create vaccines and therapies to treat the novel coronavirus.

On Friday, the National Institutes of Health and the Foundation for NIH announced the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership.

More than a dozen biopharmaceutical companies, HHS's Biomedical Advanced Research and Development Authority, the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration and the European Medicines Agency will partner to develop a strategy for a coordinated research response to the COVID-19 pandemic.

"The ACTIVE partnership will bring new levels of coordination and speed to public and private work on therapies and vaccines for COVID-19—work that NIH, HHS, and the Trump administration began literally days after the coronavirus threat was identified in China in January," HHS Secretary Alex Azar said in a statement Friday.

"To save lives and bring life back to normal in the United States and around the world, we need COVID-19 vaccines and therapies on the market as soon as possible," he continued, adding that the ACTIV partnership "will accelerate the amazing work being done every day by scientists and innovators inside and outside of government."

He added that the National Institute of Health has "an extensive track record of coordinating these development efforts for new biological threats, and they are well-suited to lead this part of the whole-of-government, whole-of-America response President Trump has marshaled to defeat COVID-19."

The announcement of the public-private partnership comes after President Trump unveiled a set of guidelines titled "Opening up America Again" and declared that the U.S. was moving on to its next stage in the fight against the coronavirus.

Trump announced a bipartisan council of lawmakers dedicated to restarting the economy,

The Trump administration's guidelines outline what individuals, businesses, health care workers and more should do over three phases in reopening the economy, with states only making it to the first phase if they see a decrease in the number of cases within their borders over 14 days.

The guidelines, which pass the decision on when to move to each phase to governors and local officials, are a reversal for Trump on comments made earlier this week that indicated he wanted to be the one deciding when the stay-at-home orders and business closures would lift.

New York Gov. Andrew Cuomo said this week, though, that the crisis will not be over until there is a vaccine, which officials say could take 12 to 18 months to happen.

"That's when it's over," he said.

Chaotic search for coronavirus treatments undermines efforts, experts say

Federal officials say they are devising plans for a wide-ranging partnership to organize research

Washington Post

April 15, 2020

By Carolyn Johnson

In a desperate bid to find treatments for people sickened by the coronavirus, doctors and drug companies have launched more than 100 human experiments in the United States, investigating experimental drugs, a decades-old malaria medicine and cutting-edge therapies that have worked for other conditions such as HIV and rheumatoid arthritis.

Development of effective treatments for covid-19, the disease the virus causes, would be one of the most significant milestones in returning the United States to normalcy. But the massive effort is disorganized and scattershot, harming its prospects for success, according to multiple researchers and health experts. Researchers working around-the-clock describe a lack of a centralized national strategy, overlapping efforts, an array of small-scale trials that will not lead to definitive answers and no standards for how to prioritize efforts, what data to collect or how to share it to get to answers faster.

"It's a cacophony — it's not an orchestra. There's no conductor," said Derek Angus, chair of the department of critical care medicine at University of Pittsburgh School of Medicine, who is leading a covid-19 trial that will test multiple therapies. "My heart aches over the complete chaos in the response."

The global biomedical research establishment could be one of most powerful assets in the campaign against the new virus, with experts all over the world — and especially the scientific and medical powerhouse of the United States — in rare alignment in their focus on a single enemy. Some large trials designed to be definitive have launched. But with more than 500 human clinical trials worldwide, the lack of coordination puts the world at risk of ending up with a raft of inconclusive and conflicting studies and little idea of what interventions work for the next wave of illness.

Francis Collins, director of the National Institutes of Health, the nation's largest biomedical research agency, acknowledged researchers' frustrations but said in an interview Wednesday he has been working behind the scenes to launch an unprecedented public-private partnership to address the problems. He said the framework involves top pharmaceutical companies such as Pfizer and Johnson & Johnson, domestic and international government agencies including the European Medicines Agency, and academic research centers.

Collins said the month-long discussions have been kept under wraps to ensure buy-in for an approach likely to require sacrifices of personal recognition, scientific credit and profit — a centralized decision, for example, not to proceed with tests of one company's drug in order to move faster on a competitor's.

"I think we have the necessary clout to steer this whole complicated ecosystem," he said. "When you look at some of the things that are happening sporadically, we may be unlikely to learn what we need to from such disconnected, small trials. The whole point is to replace that with a coherent, evidence-based approach. ... I want to know what works, and I want to have it answered by June or July."

Agency officials said further details would be released in coming days.

Anthony S. Fauci, director of the National Institute of Allergy and Infectious Diseases (NIAID), said in an email Tuesday that the partnership led by Collins is the "functional equivalent of a National Strategy."

While Collins was working on developing that strategy, hospitals, drug companies, government labs and individual doctors were flooding the system with proposals for drugs and other interventions to test against the virus — an outpouring that reveals how siloed and fragmented the research enterprise remains. For example, there are more than two dozen separate U.S. trials listed for the anti-malarial drug hydroxychloroquine, all with different designs. Some use the drug as a preventive, others as a treatment. Some use it alone, some with other drugs or vitamins, and some have no comparison group to tell if the drug was responsible for the outcome. That will make it more difficult to conclude whether, or in what circumstances, the drug may work.

Collins said a working group is addressing this problem by sifting through about 100 possible covid-19 treatments to decide which are the six to eight most promising drugs to move forward in large-scale trials. Those will be deployed in large clinical trial networks.

The new federal effort is motivated in part by what happened in China. Clifford Lane, deputy director for clinical research and special projects at NIAID, traveled to the origin of the outbreak in February as part of an international delegation to help the world learn from the Chinese experience. He was troubled by the lack of a strategic plan to prioritize and fast-track the most promising treatments, leading to a mosaic of inconclusive findings.

"We do have to have a bigger strategy than every university, every institute and — to be blunt — every country" working on their own research efforts, Lane said in an interview.

At the heart of the problem is the basic question of whether a drug really works. Typically, drugs and medical interventions are first tested in small clinical trials that establish safety before the most promising ones are funneled into bigger trials, in an iterative and years-long process. These trials, which typically randomly assign patients to receive either a drug or a placebo, prove that medicines, vaccines and medical procedures are effective and safe. But with the urgency of the coronavirus threat, timelines have been squeezed, doctors are doing uncontrolled experiments as they administer regular care, and the typical model for research is too slow.

Prioritizing research

David Boulware, an infectious-disease physician and scientist at the University of Minnesota, has gotten at least 50 emails from companies and researchers with treatments they want to test. The urgency to find something — anything — for patients who have nothing other than supportive care has led researchers to pull everything off the shelf: a mix of existing drugs that show promise, stem cell treatments and brand new compounds designed specifically against covid-19.

The energy is remarkable, but it needs to be channeled. Clinical trials, whether for an HIV drug or a brand new medicine, compete for many of the same patients. If there are too many trials at a hospital, none of them may enroll enough patients

to get clear results. If there are too many similar small trials running in parallel, their results individually may be inconclusive and the data could have so many differences they may not be able to be pooled.

"There's all sorts of people wanting to try anything, because people are desperate," Boulware said.

He and others who were unaware of Collins's plans argue that national leadership — whether guidance on how to prioritize trials, a central body coordinating efforts, or a mechanism to play matchmaker among institutions working on similar ideas — could help channel the ubiquitous scientific desire to make a bigger, faster impact.

Some large-scale efforts are already underway: The World Health Organization has organized a massive trial in 90 countries of four promising therapies. The National Institutes of Health is conducting a test of the antiviral medication remdesivir at more than 50 institutions and last week launched a large trial for an anti-malarial medication. A \$50 million effort at the Duke Clinical Research Institute will test hydroxychloroquine in 15,000 health-care workers and create a registry that can be tapped to speed up future trials, such as for a vaccine.

"People should not be fatalistic that we're going to have a paucity of evidence for things that provide benefit," Collins said. "I hope we'll have three to four of those [treatments] by the summer."

But as the federal effort has proceeded largely in secret, individual institutions have scrambled to set up committees of experts who evaluate which trials make sense to move forward. At the University of Pennsylvania, a weeks-old committee gives priority scores to trials based on criteria such as whether they will compete with existing efforts and how they are to enroll all the patients needed to get a result. A task force at Duke University does a similar review.

"There's a lot of stuff bubbling up. It would seem like a sensible thing to do would be to align everyone around the same trials, not one trial for each context and not have each institution do its own thing and at the end of the day everyone has done a small trial ... and we don't know what to make of it," said Steven Joffe, a bioethicist at the University of Pennsylvania. "Let's get to an answer."

Many proposed trials overlap — using the same drug, such as the anti-malaria treatment hydroxychloroquine that has been touted by President Trump, his personal lawyer Rudolph W. Giuliani and conservative talk show host Laura Ingraham.

Boulware is halfway through one such hydroxychloroquine trial, which examines whether the drug is effective at preventing the disease or in treating people with mild cases. People who participate will receive either the drug or a vitamin in the mail.

He said he is motivated by his experience working on Ebola, when by the time a well-designed trial was up and running, the outbreak was dying down. He plowed ahead with his hydroxychloroquine trial weeks before he heard — last Friday — the National Institutes of Health had declined to fund it. He found international collaborators through chance and social media when some Canadian researchers emailed to ask if he would share his trial design with them. He ended up connecting the Canadians with each other and is now working on overcoming the complex legal requirements to share data.

But now, his trial is potentially competing with a bunch of others that also test hydroxychloroquine all across the country — and enrollment has slowed in recent days.

Risks of inconclusive evidence in the social media age

Small trials and even anecdotal reports of treatments that appear to have worked on small groups of patients already are being shared, sowing both hope and confusion about the evidence.

A study published Friday in the New England Journal of Medicine reported on 53 people who took remdesivir, a failed Ebola drug Trump has praised and many families have tried to access outside of trials. The results were impossible to interpret, though, since some of those patients might have gotten better on their own and there was no comparison group of patients who did not receive the drug. Hydroxychloroquine, the cheap and readily available anti-malarial drug, also already has been widely used in patients despite only suggestive evidence it might work.

As more small-scale studies are designed, the risks of inconclusive but suggestive results multiply — and paradoxically, they could make it harder to conduct well-designed clinical trials that get to the bottom of whether a treatment works. Well-designed clinical trials require patients to be willing to be randomly assigned to receive the treatment — or a placebo.

Emma Meagher, chief clinical research officer at the University of Pennsylvania's Perelman School of Medicine, said her institution's study of the malaria drug in severely ill patients does not have a comparison group that receives a placebo

because the media around the drug has made it the standard of care despite the lack of evidence. Every meeting, she said, begins with a discussion about how to prevent the next experimental therapy from becoming like hydroxychloroquine.

In some ways, designing research studies when clinicians have an imperative to give their patients the best care possible is an inherently tricky situation. Outside of top-tier research hospitals, patients may not have access to trials, so clinicians may have little option but to give them drugs in what amounts to an uncontrolled experiment. The Infectious Diseases Society of America released guidelines last week recommending that clinicians should give experimental drugs only in trials, but safety-net and rural hospitals are less likely to have access to those.

"Do we really want to have [some] people trying new different things and the rest of you sit and wait?" asked Benjamin Linas, an infectious-disease physician working on oversight of clinical trial protocols at Boston Medical Center.

Lost time

Many researchers have said they are hopeful a national strategy will help unify and speed up the search but lament the time already lost. The United States did not have a pandemic clinical trials network ready to be activated, but existing clinical trials networks, such as those used to test HIV treatments, are now being repurposed. Collins said he had never seen research move faster, but in a pandemic that can still feel slow.

"We have imperfect networks. I mean, there are some there, but they've never been tested in this way," said Adrian Hernandez, vice dean for clinical research at Duke University School of Medicine. "Having a common infrastructure that can do rapid-cycle trials — that would be beneficial."

Collins said he began partnering with private companies, research institutions and other agencies in mid-March. Had he started sooner, he said, the urgency of the situation might not have been clear to those groups he had to convince to work together. He disagrees significant time has been lost and noted the efforts were able to piggyback on an existing framework for pursuing drugs with industry collaboration called the Accelerating Medicines Partnership.

Partnerships that previously took a year and a half to build were put together in a week, he said.

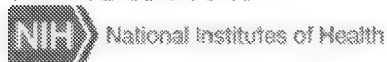
"I think it is a world record for anything of this sort. It might have been difficult to get full unanimous agreement to what is clearly unprecedented — for a willingness to give up control," Collins said.

As with other areas of pandemic planning, many hope the United States will learn from this lesson, that it needs a preparedness plan not only for allocating essential supplies and scaling up testing but also in plotting research.

"The problem is we need to remember to invest in preparedness, at times when we're not affected with a pandemic or epidemic," said Barbara Bierer, director of the regulatory foundations, ethics and the law program of the Harvard Clinical and Translational Science Center. "And it's hard to repurpose or commit resources to something that doesn't appear immediate on the horizon."

Thank you,
Ashley

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Office of the Director | National Institutes of Health
Tel: 301-594-7743



From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 5/17/2020 6:10:12 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: FW: ChAdOx1
Flag: Follow up

How should we handle this? I think we agreed that calling [b4] at this point would likely not be productive. If this is a call to discuss getting [b4] vaccine on board, that is another matter. Thoughts?

From: Marks, Peter [b6]
Sent: Saturday, May 16, 2020 3:13 PM
To: Fauci, Anthony (NIH/NIAID) [E] [b6]; Mascola, John (NIH/VRC) [E] [b6]
Collins, Francis (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]
Cc: Wholley, David (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: ChAdOx1

Dear Tony,

Will certainly include you next week on this call.

Best Regards,
Peter

From: Fauci, Anthony (NIH/NIAID) [E] [b6]
Sent: Thursday, May 14, 2020 9:12 AM
To: Marks, Peter [b6]; Mascola, John R (NIH) [b6]; Collins, Francis S (NIH) [b6]; Lane, Henry C (NIH) [b6]
Cc: Wholley, David N (NIH) [b6]; Tabak, Lawrence A (NIH) [b6]; Parker, Ashley S (NIH) [b6]
Subject: RE: ChAdOx1

I would also like to be on that call with the [b4] CEO if we could possible arrange it.

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases
Building 31, Room 7A-03
31 Center Drive, MSC 2520
National Institutes of Health
Bethesda, MD 20892-2520
Phone: [b6]
FAX: (301) 496-4409
E-mail: [b6]

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COLL0000016959-2441848

From: Marks, Peter [REDACTED] b6
Sent: Thursday, May 14, 2020 9:05 AM
To: Mascola, John (NIH/VRC) [E] [REDACTED] b6 Collins, Francis (NIH/OD) [E] [REDACTED] b6 Lane, Cliff (NIH/NIAID) [E] [REDACTED] b6
Cc: Fauci, Anthony (NIH/NIAID) [E] [REDACTED] b6 Wholley, David (FNIH) [T] [REDACTED] b6 Tabak, Lawrence (NIH/OD) [E] [REDACTED] b6 Parker, Ashley (NIH/OD) [E] [REDACTED] b6
Subject: RE: ChAdOx1

Dear John,

Thanks for bringing the [REDACTED] b4 issue up. I think that a call with their head of development and possibly also their CEO may be needed, and I wonder if Francis would like to join?

Best Regards,
Peter

From: Mascola, John (NIH/VRC) [E] [REDACTED] b6
Sent: Thursday, May 14, 2020 9:03 AM
To: Marks, Peter [REDACTED] b6 Collins, Francis S (NIH) [REDACTED] b6 Lane, Henry C (NIH) [REDACTED] b6
Cc: Fauci, Anthony S (NIH) [REDACTED] b6 Wholley, David N (NIH) [REDACTED] b6 Tabak, Lawrence A (NIH) [REDACTED] b6 Parker, Ashley S (NIH) [REDACTED] b6
Subject: RE: ChAdOx1

Francis - we did make good progress on ACTIV Vaccine WG. Yesterday on the vaccine clinical trials subgroup, we presented the harmonized protocol approach and high level details of phase 3 design. There was good input on both and general agreement, with some useful recommendations on efficient ways to conduct phase 3.

One issues is that [REDACTED] b4
[REDACTED] b4
[REDACTED] b4. When we asked for suggestions for DSMB, Kathrin said she did not agree that we should ask for nominations – because this issue required more discussion – [REDACTED] b4
[REDACTED] b4 Doug Lowy was on the call, so may be useful to get his perspective.

John

From: Marks, Peter [REDACTED] b6
Sent: Thursday, May 14, 2020 6:23 AM
To: Collins, Francis (NIH/OD) [E] [REDACTED] b6 Mascola, John (NIH/VRC) [E] [REDACTED] b6 Lane, Cliff (NIH/NIAID) [E] [REDACTED] b6
Cc: Fauci, Anthony (NIH/NIAID) [E] [REDACTED] b6 Wholley, David (FNIH) [T] [REDACTED] b6 Tabak, Lawrence (NIH/OD) [E] [REDACTED] b6 Parker, Ashley (NIH/OD) [E] [REDACTED] b6
Subject: RE: ChAdOx1

Dear Francis,

We had made good progress with the Oxford AZ team on the clinical end before the contracting period began. From my last conversation with the AZ clinical team they were on board with the USG concept of a large phase 3 trial, potentially as part of a master protocol if the timing was right. Their major issue was getting moving rapidly.

Among other things, Tony, John and I discussed the concept that in addition to harmonized protocols we would consider merging the first two vaccines that are currently aiming to start phase 3 into one master protocol if they appeared to be staying on schedule for a July 1 start. Planning on one DSMB for at least these two candidates therefore makes a lot of sense.

Later today I will be speaking with John again about this merged concept. After giving it very careful consideration, though it certainly involves significant extra work in protocol development and logistic planning, I believe that we should be actively planning for the two contingencies simultaneously:

- 1) Moderna and Oxford AZ enter phase 3 at different times (more than 2 weeks apart), in which case we will go with harmonized protocols, non-overlapping sites, and a single DSMB, and
- 2) Moderna and Oxford AZ enter phase 3 simultaneously (less than 2 weeks apart), in which case we should plan on one master protocol making use of all available sites. There is much to recommend this option, such that it is worth the effort in planning even if circumstances preclude proceeding along this path: 1) it could reduce the overall size of the trials by 10,000; 2) could help drive enrollment since fewer people will receive placebo; and 3) it will produce comparative efficacy data.

[b4]
[b4] that will have to be addressed, but these do not appear to be showstoppers. Happy to discuss further.

Best Regards,
Peter

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 5:38 AM
To: Mascola, John R (NIH) [b6]; Lane, Henry C (NIH) [b6]; Marks, Peter [b6]
Cc: Fauci, Anthony S (NIH) [b6]; Wholley, David N (NIH) [b6]; Tabak, Lawrence A (NIH) [b6]; Parker, Ashley S (NIH) [b6]
Subject: ChAdOx1

Gentlemen:

I need to know the update on where we are with Oxford, A-Z, and ChAdOx1. I see there's a BARDA WebEx at 5 pm, and I have a rescheduled phone call this morning with John Bell. I'd like to be as useful as possible in making a plan that includes this vaccine program as part of the harmonized master protocol. Advice about how to use the call with John Bell most effectively would be most welcome!

And did the Vaccines WG make good progress yesterday on the details of the harmonized master protocol? [b4,b5]
agree in principle to a single DSMB?

Thanks, Francis

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/17/2020 8:18:06 PM
To: Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Sandeep Menon [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f29042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price [b6]
CC: Demarcus [b6]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; [b6] Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa [b6]; Eron, Joseph J Jr [b6]; Smith, David [b6]; Paul Klekotka [b6]
Subject: ACTIV TX-Clinical Master Protocol Outpatient mAbs Writing Team Meeting #1
Attachments: a5401-d03-activ-051620.docx
Location: [b6]
Start: 5/18/2020 5:00:00 PM
End: 5/18/2020 6:00:00 PM
Show Time As: Tentative

Required Attendees: Judy Currier; Eric Hughes; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; [b6]
Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Jhoanna Roa; [b6] Eron, Joe; Javan, Arzhang (NIH/NIAID) [E]; Roa, Jhoanna; [b6] Kim, Peter (NIH/NIAID) [E]
Required Attendees: Eron, Joseph J Jr; Smith, David; Paul Klekotka

Updated with New Protocol Version

Dear ACTIV-2 Master Protocol Writing Team,

Thank you all for being willing to get together so quickly. I look forward to the ACTIV and the ACTG teams working together to make this protocol great and get it going quickly.

APAR0000005387-2442203

We will work to get a full list of participants and their roles together for this meeting to distribute. In the meantime, the ACTG team has been kind enough to send the current draft of their protocol for us to start from. They have noted to me that they have removed some agent specific information for confidentiality purposes, but all else should be ready for this group to review and start thinking and commenting on.

Thanks,

Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/17/2020 8:20:20 PM
To: Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [b6] LaVange, Lisa M [b6] Sandeep Menon [b6] Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price [b6]
[b6] Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; [b6] Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Smith, David [b6]; Paul Klekotka [b6]; Jhoanna Roa [b6]
Eron, Joseph J Jr [b6]
CC: Demarcus [b6] Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: NEW PROTOCOL VERSION for ACTIV TX-Clinical Master Protocol Outpatient mAbs Writing Team Meeting #1
Attachments: a5401-d03-activ-051620.docx

Dear ACTIV-2 Master Protocol Writing Team,

Please find attached a new protocol version from the ACTG team for discussion at tomorrow's meeting.

Thanks,

Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [b6] Mobile: [b6]

Join Zoom Meeting

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From: Tountas, Karen (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
Sent: 5/18/2020 12:22:03 AM
To: Bascles, Lionel [b6]; Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [b6]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers, Betsy [b6]; Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshov, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshovj]; Garner, Carlos [b6]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Mensah, George (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Resnansky, Laura [b6]; Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Vincent, Mike [b6]; Wachtel, Jonathan [jwachtel@deloitte.com]; Weinmann, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang]
CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [b6]; Jansen, Kathrin [b6]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [b6]; Criffield, Robin [b6]; Hamilton, Nancy [b6]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Minnich, Beth [b6]; Mueller-Reichenstein, Petra [b6]; Pico, Dianna (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=471cb6a63c8846a69073e1e968f3964c-picodf]; Quadros, Nora [b6]; Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Hill, Zoe (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [marganderson@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Carluccio, Dana [b6]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny [b6]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [b6]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative

Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveesson, Nancy [b6] Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]

Subject: Summary and action items - CT Capacity WG meeting #8
Attachments: Clinical_Trial_Capacity_Working_Group_Meeting_9_Final.pdf

Dear Clinical Trial Capacity Working Group Members,

Attached is the summary and action items for meeting #9 (May 15, 2020) of the full working group. The next full working group meeting is scheduled for Tuesday, May 19 at 9 am eastern time USA.

Cheers!
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health
[b6] fniih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fniih.org/pandemic



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From: Myles, Renate (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7D317F5626934585B3692A1823C1B522-MYLESR]
Sent: 5/18/2020 1:37:20 PM
To: Wooldridge, Shannon (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=385b0c281f104789873e956dc91b7c06-burdense]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Pollock, Rachel (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4887cb3513e242dfa7d2df712dcc6d6a-pollockrc]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Thank you!

From: Wooldridge, Shannon (NIH/OD) [E] [b6]
Sent: Monday, May 18, 2020 9:17 AM
To: Myles, Renate (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Pollock, Rachel (NIH/OD) [E] [b6]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

No replies from Baric, Deming, or Jansen in FC's inbox. I just ran a search.

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Monday, May 18, 2020 9:16 AM
To: Parker, Ashley (NIH/OD) [E] [b6]; Pollock, Rachel (NIH/OD) [E] [b6]; Wooldridge, Shannon (NIH/OD) [E] [b6]
Subject: RE: Time sensitive: Making your ACTIV Participation Public
Importance: High

Hi Rachel and Shannon:

Would you check FC's mailbox for this information ASAP? We need to launch the webpage this morning.

Thanks,
Renate

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, May 18, 2020 7:57 AM
To: Myles, Renate (NIH/OD) [E] [b6]; Pollock, Rachel (NIH/OD) [E] [b6]; Wooldridge, Shannon (NIH/OD) [E] [b6]
Subject: Re: Time sensitive: Making your ACTIV Participation Public

Hi Renate, Rachel, and Shannon,

We've made lots of progress! Shannon — can we see if the 3 ACTIV participants responded to Dr. Collins privately over the weekend?

Thank you,
Ashley

On May 17, 2020, at 11:15 PM, Myles, Renate (NIH/OD) [E] [b6] wrote:

Hi Ashley and Rachel:

Below are the three people I did not hear from. I searched my inbox. Just wanted to double check that they didn't just respond to Francis. Thanks, Renate

Ralph Baric, Ph.D.

William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology
Professor, Department of Microbiology and Immunology
University of North Carolina, Gillings School of Global Public Health

[b6]

Damon Deming, Ph.D.

Virologist, Division of Antiviral Products, Office of New Drugs
U.S. Food and Drug Administration

[b6]

Kathrin Jansen, Ph.D.

Senior Vice President and Head of Vaccine Research and Development
Pfizer

[b6]

From: Collins, Francis (NIH/OD) [E]

[b6]

Sent: Thursday, May 14, 2020 11:00 AM

To: Collins, Francis (NIH/OD) [E]

[b6]

Cc: Myles, Renate (NIH/OD) [E]

[b6]

Meltzer, Abbey (FNIH) [T]

[b6]

Wholley, David (FNIH) [T]

[b6]

Subject: Time sensitive: Making your ACTIV Participation Public

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.**

Thanks,
Francis

Francis S. Collins, MD, PhD
NIH Director

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/18/2020 1:56:11 PM
To: George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]
Subject: FW: YOUR INPUT NEEDED: ACTIV Webpage

We will need to add the additions below to our leadership logo slide -- FYI

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Monday, May 18, 2020 9:54 AM
To: Myles, Renate (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]
Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: YOUR INPUT NEEDED: ACTIV Webpage

OK to add those leadership groups.

But I'm troubled about removing Jansen – she's the co-chair of the Vaccines WG. Let me bug her one more time.

FC

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Monday, May 18, 2020 9:35 AM
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Cc: Burklow, John (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]
Brodd, Lauren (NIH/OD) [E] [b6]
Subject: YOUR INPUT NEEDED: ACTIV Webpage
Importance: High

Hi Francis and Ashley:

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FNHI indicated that **Karuna Therapeutics, RTI, and Fred Hutchinson** should be listed as part of the Leadership Organizations, but that they defer to NIH. Please let me know if I should add these organizations to the list of Leadership Organizations?

We did not hear from the below individuals, so we plan to remove them from the website until we hear from them. I also understand there are several more individuals joining the working groups, so we'll likely have a second round of additions.

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Senior Vice President and Head of Vaccine Research and Development
Pfizer

b6

Beth Bell, M.D., MPH

Clinical Professor, Global Health
University of Washington

Thanks,
Renate

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/18/2020 1:58:33 PM
To: Wooldridge, Shannon (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=385b0c281f104789873e956dc91b7c06-burdense]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Thanks!!

From: Wooldridge, Shannon (NIH/OD) [E] [b6]
Sent: Monday, May 18, 2020 9:17 AM
To: Myles, Renate (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Pollock, Rachel (NIH/OD) [E] [b6]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

No replies from Baric, Deming, or Jansen in FC's inbox. I just ran a search.

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Monday, May 18, 2020 9:16 AM
To: Parker, Ashley (NIH/OD) [E] [b6]; Pollock, Rachel (NIH/OD) [E] [b6]; Wooldridge, Shannon (NIH/OD) [E] [b6]
Subject: RE: Time sensitive: Making your ACTIV Participation Public
Importance: High

Hi Rachel and Shannon:

Would you check FC's mailbox for this information ASAP? We need to launch the webpage this morning.

Thanks,
Renate

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, May 18, 2020 7:57 AM
To: Myles, Renate (NIH/OD) [E] [b6]; Pollock, Rachel (NIH/OD) [E] [b6]; Wooldridge, Shannon (NIH/OD) [E] [b6]
Subject: Re: Time sensitive: Making your ACTIV Participation Public

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b6

Kathrin Jansen, Ph.D.

Senior Vice President and Head of Vaccine Research and Development
Pfizer

b6

From: Collins, Francis (NIH/OD) [E] b6

Sent: Thursday, May 14, 2020 11:00 AM

To: Collins, Francis (NIH/OD) [E] b6

Cc: Myles, Renate (NIH/OD) [E] b6; Meltzer, Abbey (FNIH) [T] b6

Wholley, David (FNIH) [T] b6

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Francis

Francis S. Collins, MD, PhD
NIH Director

From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 5/18/2020 2:11:04 PM
To: [b6]
[b6] Baric, Ralph
[b6] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai];
[b6]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
[b6] Parker, Ashley (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];
[b6] Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas
[b6] Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar
[b6] CIV USARMY MEDCOM USAMRIID (USA) [b6]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy
[b6] Hughes, Eric [b6] Jansen, Kathrin
[b6] Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Kim, Elizabeth [elkim@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Wachtel, Jonathan [jwachtel@deloitte.com]; Prabhavathi Fernandes [b6]; Diamond, Michael
[b6]; Rose Li [rose.li@roseliassociates.com]; Dana Carluccio
[b6] Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [b6]; Dave Frankowski [b6]; Baric, Toni C [b6]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin [bstratton@DELOITTE.com]

Subject: ACTIV Preclinical working group (Tuesday meeting)

Location: [b6]

Start: 4/22/2020 2:00:00 PM

End: 4/22/2020 3:00:00 PM

Show Time As: Tentative

Recurrence: Weekly
every Wednesday from 10:00 AM to 11:00 AM

Required Attendees:

[b6]

[b6] Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E];
[b6] Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E];
Tomas Cihlar; [b6] ARMY MEDCOM [b6] USA

Optional Attendees: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting

[b6]

Meeting ID: [b6]

Password: [b6]

One tap mobile

[b6]

US (Germantown)
US (Chicago)

Dial by your location

[b6]

US (Germantown)
US (Chicago)
US (New York)
US (San Jose)

b6

US (San Jose)

US (Tacoma)

US (Houston)

Meeting ID: **b6**

Password: **b6**

Find your local number: **b6**

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 5/18/2020 2:12:39 PM
To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: RE: YOUR INPUT NEEDED: ACTIV Webpage

That's fine too

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Monday, May 18, 2020 10:11 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]
Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: YOUR INPUT NEEDED: ACTIV Webpage

I looked up both RTI and Fred Hutch and they are both non-profits, so perhaps we can just list them as non-profits.

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Monday, May 18, 2020 10:07 AM
To: Myles, Renate (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]
Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: YOUR INPUT NEEDED: ACTIV Webpage

I think you could expand the Non-profit category to Non-profit/Academic, and that would capture RTI and the Hutch.

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Monday, May 18, 2020 10:03 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]
Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: YOUR INPUT NEEDED: ACTIV Webpage

I will add them. The three categories we currently have are Government, Industry, and Non-Profit. Karuna falls under Industry, but what about RTI and Fred Hutchinson Cancer Center? Do we need to add an Academic category?

From: Collins, Francis (NIH/OD) [E] [b6]
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Cc: Burklow, John (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]

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Senior Vice President and Head of Vaccine Research and Development
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[b6]

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Clinical Professor, Global Health
University of Washington

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Subject: RE: YOUR INPUT NEEDED: ACTIV Webpage

Let's wait and follow what Renate post on the website today. I was only referring to the 3 – not everything below.

From: George, Jill (NIH/OD) [E] [b6]
Sent: Monday, May 18, 2020 10:17 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: YOUR INPUT NEEDED: ACTIV Webpage

Hi Ashley,
Please confirm my thoughts in RED caps. No rush.
Thanks!

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, May 18, 2020 9:56 AM
To: George, Jill (NIH/OD) [E] [b6]
Subject: FW: YOUR INPUT NEEDED: ACTIV Webpage

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Cc: Burklow, John (NIH/OD) [E] [b6] Wolinetz, Carrie (NIH/OD) [E] [b6]
Brodd, Lauren (NIH/OD) [E] [b6]
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Brodd, Lauren (NIH/OD) [E] [b6]
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William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology
Professor, Department of Microbiology and Immunology
University of North Carolina, Gillings School of Global Public Health

b6

Damon Deming, Ph.D. NO CHANGE

Virologist, Division of Antiviral Products, Office of New Drugs
U.S. Food and Drug Administration

b6

Kathrin Jansen, Ph.D. NO CHANGE UNLESS WE HEAR OTHERWISE

Senior Vice President and Head of Vaccine Research and Development
Pfizer

b6

Beth Bell, M.D., MPH (LOGO 2 UNDER ACADEMIA LEADERS)

Clinical Professor, Global Health
University of Washington

Thanks,
Renate

From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 5/18/2020 2:26:39 PM
To: [b6] Tomas Cihlar [b6]
[b6]
[b6] Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai];
[b6] Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
[b6] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];
[b6] Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas /US [b6] Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]
CC: Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [b6] Hughes, Eric [b6] Jansen, Kathrin [b6] Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4b79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Kim, Elizabeth [elkim@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Wachtel, Jonathan [jwachtel@deloitte.com]; Prabhavathi Fernandes [b6]; Diamond, Michael

[b6]; Rose Li [b6]; Dana Carluccio
[b6] Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses];
Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D
[b6] Dave Frankowski [b6]; Florence, Clint (NIH/NIAID) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; [b6]
[b6] Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]

Subject: RE: ACTIV Preclinical working group (Friday meeting)

Attachments: ACTIV PRECLINICAL_Animal Model Inventory_20200514 jpm.xlsx; Therapeutic information request form-v8.docx;
2020-05-15_Preclinical_WG_Summary_d4.docx

[Confidential and Pre-decisional]

Dear Preclinical working group members and invitees,

Thank you for a very interesting meeting on Friday. Please find the attached minutes for your review. Also, I am attaching the current therapeutic information request and the animal model inventory. Finally I have pasted the action items below.

Best regards,
Joe

Action Items:

- Dr. Jay Rappaport will share a white paper to ACTIV leadership outlining the necessary responsibilities of an NPRC coordinating group.
- Joe will share the newest version of the therapy request form to the WG after making the changes discussed. [with this email]
- Joe will send members the most recent WG animal model inventory. [with this email]
- Dr. Srinivas Rao will lead the WG in developing IP protection strategies by generating a first draft of the topics that need to be addressed.
- Dr. Rappaport will share guidelines on how the NPRCs enable academic researchers to publish data derived from research that uses IP.

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T]

Sent: Tuesday, April 14, 2020 6:48 PM

To: [b6]; Tomas Cihlar; [b6] Menetski, Joseph (FNIH) [T];

[b6]

[b6] Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; [b6] Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas /US; Anderson, James (NIH/OD) [E]; Qashu, Felicia (NIH/OD) [E]

Cc: Nancy Haigwood; Lowy, Douglas (NIH/NCI) [E]; Simon, Dina (NIH/OD) [C]; Wholley, David (FNIH) [T]; Austin,

Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Florence, Clint (NIH/NIAID) [E]; [b6] Hild, Sheri (NIH/OD) [E]

Subject: ACTIV Preclinical working group (Friday meeting)

When: Friday, May 15, 2020 11:00 AM-12:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: [b6]

Holding time

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting

[b6]

Meeting ID: [b6]

Password: [b6]

One tap mobile

[b6] US (New York)
[b6] US (Chicago)

Dial by your location

[b6] US (New York)
[b6] US (Chicago)
[b6] US
[b6] US
[b6] US (Houston)
[b6] US (San Jose)
[b6] US (San Jose)

Meeting ID: [b6]

Password: [b6]

Find your local number: [b6]

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 5/18/2020 2:29:24 PM
To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]
Subject: RE: NOW REALLY URGENT, need your response: Making your ACTIV Participation Public

Yes.

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Monday, May 18, 2020 10:27 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: RE: NOW REALLY URGENT, need your response: Making your ACTIV Participation Public

Should we just include her? I need to push the website live.

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Monday, May 18, 2020 9:58 AM
To: [b6]
Cc: Myles, Renate (NIH/OD) [E] [b6]
Subject: NOW REALLY URGENT, need your response: Making your ACTIV Participation Public

Hi Kathrin,

Sorry to keep bugging you, and it's possible we missed seeing your earlier response, but is it OK to list you on the ACTIV web site? As co-chair of the Vaccines WG, it would be very unfortunate to omit you – and yet we wanted to get permission before doing so. We want to post this imminently today.

Thanks, Francis

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Saturday, May 16, 2020 6:02 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Myles, Renate (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: URGENT, need your response: Making your ACTIV Participation Public

Dear ACTIV Colleagues:

Yes, this follow up and increasingly urgent message is for you, even though your address was in the bcc line! We have heard from almost all of the ACTIV Working Group participants, and so far all have been happy to have their names listed in the ACTIV web site. But we still haven't heard from YOU.

Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please don't delay further, and send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 5 p.m. ET tomorrow, Sunday May 17.**

Thanks,
Francis

Francis S. Collins, MD, PhD
NIH Director

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 5/18/2020 3:46:05 PM
To: Jansen, Kathrin [b6]
CC: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]
Subject: RE: NOW REALLY URGENT, need your response: Making your ACTIV Participation Public
Flag: Follow up

Thanks!

From: Jansen, Kathrin [b6]
Sent: Monday, May 18, 2020 11:01 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Myles, Renate (NIH/OD) [E]
Subject: RE: NOW REALLY URGENT, need your response: Making your ACTIV Participation Public

Dear Francis, I missed my deadline, thanks for the prompt. Ok to use my name as a co-chair. Best Kathrin

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Monday, May 18, 2020 9:58 AM
To: Jansen, Kathrin [b6]
Cc: Myles, Renate (NIH/OD) [E] [b6]
Subject: [EXTERNAL] NOW REALLY URGENT, need your response: Making your ACTIV Participation Public

Hi Kathrin,

Sorry to keep bugging you, and it's possible we missed seeing your earlier response, but is it OK to list you on the ACTIV web site? As co-chair of the Vaccines WG, it would be very unfortunate to omit you – and yet we wanted to get permission before doing so. We want to post this imminently today.

Thanks, Francis

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Saturday, May 16, 2020 6:02 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Myles, Renate (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: URGENT, need your response: Making your ACTIV Participation Public

Dear ACTIV Colleagues:

Yes, this follow up and increasingly urgent message is for you, even though your address was in the bcc line! We have heard from almost all of the ACTIV Working Group participants, and so far all have been happy to have their names listed in the ACTIV web site. But we still haven't heard from YOU.

Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please don't delay further, and send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 5 p.m. ET tomorrow, Sunday May 17.**

COLL0000020335

Thanks,
Francis

Francis S. Collins, MD, PhD
NIH Director

From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
Sent: 5/18/2020 7:21:29 PM
To: [b6]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; [b6]; Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbf6108d53148f684dad333fce983de-aarvin.stan]; Beth Bell [b6]; Cavaleri Marco [b6]; [b6]; Greg Glenn [b6]; Haynes, Barton [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d4a05845b5b4069ad0447fb60ebfa79-hayne002.mc]; [b6]; [b6]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; [b6]; USARMY [b6] (USA) [b6]; Offit, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbd9cc56fdb4598a57b423d484dcf9f-offit.email]; [b6]; Seals, Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a87d49ccb4e3caaf5eb5d3586b1cc-Jonathan.Se]; [b6]; Tal Zaks [b6];
CC: Tolman, Brett [btolman@deloitte.com]; [b6]; Hopps, Markay [b6]; Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; Johnson, Maureen (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr]; [b6]; Jeneffer Haynes [b6]; [b6]; [b6]; [b6]; Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; [b6]; Isabel Ramsey [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [b6]; Hughes, Eric [b6]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John

[b6]; Paul Gillard [b6]; Hamilton, Holli (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a28fc2f8eb134b00b5eaa4222d0576cc-Holli.Hamil]; Modjarrad, Kayvon CIV USARMY [b6] (USA) [b6]; Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33958e1252cf4266bffc8d94988f5715-kneuzil.som]; Schrag, Stephanie (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9be29b344ba14363bdecaa43582ca226-ZHA6]; Verani, Jennifer R. (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c249692151d46d6ac80cb28ada3d3a0-qzr7]; Thornburg, Natalie (CDC/DDID/NCIRD/DVD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c8d079e00a5649639c6f1425f3bb075f-nax3]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Wachtel, Jonathan [jwachtel@DELOITTE.com]; Stratton, Benjamin [bstratton@DELOITTE.com]; Anderson, Margaret [b6]; Bethany Stokes

Subject: ACTIV Vaccines Working Group meeting

Location: [b6]

Start: 5/28/2020 6:00:00 PM

End: 5/28/2020 7:00:00 PM

Show Time As: Tentative

Required Attendees: [b6] Lowy, Douglas (NIH/NCI) [E]; [b6] Arvin, Ann; Beth Bell [b6]; [b6] Cavaleri Marco; [b6] Greg Glenn; [b6] Haynes, [b6] Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); [b6] ARMY [b6] (USA); Offit, Paul; [b6] Seals, Jonathan (OS/ASPR/BARDA); [b6] Tal Zaks

Optional Attendees: Tolman, Brett; [b6] Hopps, Markay; Kozlowski, Mary (NIH/NCI) [C]; Johnson, Maureen (NIH/NCI) [E]; [b6] Jeneffer Haynes; [b6] Austin, Sarah (NIH/NIAID) [E]; [b6] Isabel Ramsey; Parker, Ashley (NIH/OD) [E]; Marston, Hilary (NIH/NIAID) [E]; Qashu, Felicia (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James, Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Kurilla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Paul Gillard; Hamilton, Holli (OS/ASPR/BARDA); Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA); Kathleen Neuzil; Schrag, Stephanie (CDC/DDID/NCIRD/DBD); Verani, Jennifer R. (CDC/DDID/NCIRD/DBD); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Gonzalez, Nina; Wachtel, Jonathan; Stratton, Benjamin; Anderson, Margaret; [b6] Bethany Stokes

-- Do not delete or change any of the following text. --

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[b6] Call-in toll number (US/Canada)

Global call-in numbers

Join using Microsoft Lync or Microsoft Skype for Business

Dial

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Sent: 5/18/2020 7:21:31 PM
To: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr];

[b6]; Lowy, Douglas (NIH/NCI) [E] [b6]
Arvin, Ann [b6]; Beth Bell [b6]
[b6]; Cavaleri Marco [b6]
[b6] Greg Glenn [b6]
[b6] Haynes, Barton [b6]
Marks, Peter (FDA/CBER) [b6]; Mascola, John (NIH/VRC) [E] [b6]
Messonnier, Nancy (CDC/DDID/NCIRD/OD) [b6] [b6] USARMY [b6]
(USA) [b6]; Offit, Paul [b6] Seals, Jonathan (OS/ASPR/BARDA)
[b6]; Tal Zaks [b6]
CC: Tolman, Brett [btolman@deloitte.com]; [b6] Hopps, Markay [b6]
Kozlowski, Mary (NIH/NCI) [C] [b6] Johnson, Maureen (NIH/NCI) [E]
[b6] Jeneffer Haynes [b6]
[b6] Austin, Sarah (NIH/NIAID) [E]
[b6] Isabel Ramsey [b6] Parker,
Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Marston, Hilary (NIH/NIAID) [E] [b6]; Qashu, Felicia (NIH/OD) [E] [b6]; Culp, Michelle (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6] Tountas, Karen (FNIH) [T] [b6]
James, Stephanie (FNIH) [T] [b6] Colvis, Christine (NIH/NCATS) [E] [b6]
Desrosiers, Betsy [b6] Kurilla, Michael (NIH/NCATS) [E] [b6]
Read, Sarah (NIH/NIAID) [E] [b6] Young, John [b6]; Paul Gillard [b6]
Hamilton, Holly (OS/ASPR/BARDA) [b6]; Modjarrad, Kayvon CIV USARMY [b6] (USA) [b6] Kathleen Neuzil [b6]
Schrag, Stephanie (CDC/DDID/NCIRD/DBD) [b6] Verani, Jennifer R. (CDC/DDID/NCIRD/DBD) [b6]; Thornburg, Natalie (CDC/DDID/NCIRD/DBD) [b6]; Gonzalez, Nina [ningonzalez@deloitte.com]; Wachtel, Jonathan [jwachtel@DELOITTE.com]; Stratton, Benjamin [bstratton@DELOITTE.com]; Anderson, Margaret [b6]
[b6] Bethany Stokes [b6] Arvin, Ann [b6] Biggerstaff, Matthew (CDC/DDID/NCIRD/ID) [b6] Cohen, Myron [b6] Erbelding, Emily (NIH/NIAID) [E] [b6]
[b6] Gruber, Marion (FDA/CBER) [b6]; [b6] Ledgerwood, Julie (NIH/NIAID) [E] [b6] Marovich, Mary (NIH/NIAID) [E] [b6] Laurent Humeau [b6]
[b6] Cheryl Keech [b6]; Hughes, Eric [b6]
Denny, Joshua (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd64626dabbb45aa8b8e5d21169344e6-dennyjc]

Subject: ACTIV Vaccines Working Group meeting

Location: [b6]

Start: 5/28/2020 6:00:00 PM

End: 5/28/2020 7:00:00 PM

Show Time As: Busy

Required Attendees: [b6] Lowy, Douglas (NIH/NCI) [E]; [b6] Arvin, Ann; Beth Bell [b6] Haynes, [b6]

**Optional
Attendees:**

Barton; [b6]; Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E];
Messonnier, Nancy (CDC/DDID/NCIRD/OD); [b6] USARMY [b6] (USA); Offit, Paul;
[b6]; Seals, Jonathan (OS/ASPR/BARDA); [b6]; Tal Zaks
Tolman, Brett; [b6] Hopps, Markay; Kozlowski, Mary (NIH/NCI) [C]; Johnson, Maureen
(NIH/NCI) [E]; [b6] Jeneffer Haynes; [b6]
[b6] Austin, Sarah (NIH/NIAID) [E]; [b6] Isabel Ramsey; Parker,
Ashley (NIH/OD) [E]; Marston, Hilary (NIH/NIAID) [E]; Qashu, Felicia (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E];
Gadbois, Ellen (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T];
Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James, Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E];
Desrosiers, Betsy; Hughes, Eric; Kurilla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Paul
Gillard; Hamilton, Holli (OS/ASPR/BARDA); [b6] USARMY MEDCOM [b6] (USA); Kathleen Neuzil;
Schrage, Stephanie (CDC/DDID/NCIRD/DBD); Verani, Jennifer R. (CDC/DDID/NCIRD/DBD); Thornburg, Natalie
(CDC/DDID/NCIRD/DVD); Gonzalez, Nina; Wachtel, Jonathan; Stratton, Benjamin; Anderson, Margaret;
[b6] Bethany Stokes; Ann Arvin; Biggerstaff,
Matthew (CDC/DDID/NCIRD/ID); Cohen, Myron; Denny, Joshua (NIH/OD) [E]; [b6]; Erbelding,
Emily (NIH/NIAID) [E]; [b6]; Gruber, Marion (FDA/CBER);
[b6] [b6] Ledgerwood, Julie (NIH/NIAID) [E];
[b6] Marovich, Mary (NIH/NIAID) [E]; [b6]
'Laurent Humeau'; [b6] Cheryl Keech

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Sent: 5/18/2020 7:21:48 PM
To: [b6] Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; [b6] Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbf6108d53148f684dad333fce983de-aarvin.stan]; Beth Bell [b6] Cavaleri Marco [b6] [b6] Greg Glenn [b6] Haynes, Barton [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d4a05845b5b4069ad0447fb60ebfa79-hayne002.mc]; [b6] [b6] Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; [b6] USARMY [b6] (USA) [b6] Offit, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cdb9cc56fdb4598a57b423d484dcf9f-offit.email]; [b6] Seals, Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a87d49ccb4e3caaf5eb5d3586b1cc-Jonathan.Se]; [b6] Tal Zaks [b6]
CC: Tolman, Brett [btolman@deloitte.com]; [b6]; Hopps, Markay [b6] Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; Johnson, Maureen (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr]; [b6] Jeneffer Haynes [b6] [b6] Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; [b6] Isabel Ramsey [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702f2c28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [b6] Hughes, Eric [b6] Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John

[b6] Paul Gillard [b6]; Hamilton, Holli (OS/ASPR/BARDA)
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=a28fc2f8eb134b00b5eaa4222d0576cc-Holli.Hamil]; [b6]
 USARMY [b6] (USA) [b6]; Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange
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 Schrag, Stephanie (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (CDC/DDID/NCIRD/DVD) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=c8d079e00a5649639c6f1425f3bb075f-nax3]; Gonzalez, Nina
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
 Wachtel, Jonathan [jwachtel@DELOITTE.com]; Stratton, Benjamin [bstratton@DELOITTE.com]; Anderson, Margaret
 [marganderson@deloitte.com]; [b6] Bethany Stokes
 [b6]

Subject: ACTIV Vaccines Working Group meeting

Location: [b6]

Start: 6/4/2020 6:15:00 PM

End: 6/4/2020 7:15:00 PM

Show Time As: Tentative

Required Attendees: [b6] Lowy, Douglas (NIH/NCI) [E]; [b6] Arvin, Ann; Beth Bell
 [b6] Cavaleri Marco; [b6]
 [b6] Greg Glenn; [b6] Haynes,
 Barton; [b6] Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E];
 Messonnier, Nancy (CDC/DDID/NCIRD/OD); [b6] USARMY [b6] (USA); Offit, Paul;
 [b6] Seals, Jonathan (OS/ASPR/BARDA); [b6] Tal Zaks
Optional Attendees: Tolman, Brett; [b6] Hopps, Markay; Kozlowski, Mary (NIH/NCI) [C]; Johnson, Maureen
 (NIH/NCI) [E]; [b6] Jeneffer Haynes; [b6]
 [b6] Austin, Sarah (NIH/NIAID) [E]; [b6]; Isabel Ramsey; Parker,
 Ashley (NIH/OD) [E]; Marston, Hilary (NIH/NIAID) [E]; Qashu, Felicia (NIH/OD) [E]; Wholley, David (FNIH) [T];
 Melencio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James,
 Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Kurilla, Michael (NIH/NCATS)
 [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Paul Gillard; Hamilton, Holli (OS/ASPR/BARDA); [b6]
 USARMY [b6] (USA); Kathleen Neuzil; Schrag, Stephanie (CDC/DDID/NCIRD/DBD); Verani, Jennifer R.
 (CDC/DDID/NCIRD/DBD); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Gonzalez, Nina; Wachtel, Jonathan; Stratton,
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Sent: 5/18/2020 7:21:49 PM
To: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr];
[b6] Lowy, Douglas (NIH/NCI) [E] [b6]
Arvin, Ann; [b6] Beth Bell [b6]
[b6] Cavaleri Marco [b6]
[b6] Haynes, Barton [b6]
Marks, Peter (FDA/CBER) [b6]; Mascola, John (NIH/VRC) [E] [b6];
Messonnier, Nancy (CDC/DDID/NCIRD/OD) [b6] USARMY MEDCOM WRAIR (USA) [b6] Offit, Paul [b6] Seals, Jonathan (OS/ASPR/BARDA) [b6]; Tal Zaks
[b6]
CC: Tolman, Brett [btolman@deloitte.com]; [b6] Hopps, Markay [b6]
Kozlowski, Mary (NIH/NCI) [C] [b6]; Johnson, Maureen (NIH/NCI) [E]
[b6]; Jeneffer Haynes [b6]
[b6] Austin, Sarah (NIH/NIAID) [E]
[b6] Isabel Ramsey [b6] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Marston, Hilary (NIH/NIAID) [E] [b6]; Qashu, Felicia (NIH/OD) [E] [b6] Culp, Michelle (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T]
[b6] Melencio, Cheryl (FNIH) [T] [b6] Menetski, Joseph (FNIH) [T]
Adam, Stacey (FNIH) [T] [b6] Tountas, Karen (FNIH) [T] [b6]
James, Stephanie (FNIH) [T] [b6] Colvis, Christine (NIH/NCATS) [E] [b6]
Desrosiers, Betsy [b6] Hughes, Eric [b6]; Kurilla, Michael (NIH/NCATS) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6] Young, John [b6] Paul Gillard [b6]; Hamilton, Hollie (OS/ASPR/BARDA) [b6] CIV USARMY MEDCOM WRAIR (USA) [b6] Kathleen Neuzil [b6] Schrag, Stephanie (CDC/DDID/NCIRD/DBD) [b6] Verani, Jennifer R. (CDC/DDID/NCIRD/DBD) [b6]; Thornburg, Natalie (CDC/DDID/NCIRD/DVD) [b6]; Gonzalez, Nina [ningonzalez@deloitte.com]; Wachtel, Jonathan [jwachtel@DELOITTE.com]; Stratton, Benjamin [bstratton@DELOITTE.com]; Anderson, Margaret [marganderson@deloitte.com]; [b6] Bethany Stokes [b6] Arvin, Ann [b6] Vivek Shinde [b6]

Subject: ACTIV Vaccines Working Group meeting

Location: [b6]

Start: 6/4/2020 6:15:00 PM

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Required Attendees: Santos, Michael (FNIH) [T]; [b6] Lowy, Douglas (NIH/NCI) [E]; [b6]
Arvin, Ann; Beth Bell [b6]; Cavaleri Marco; [b6]
[b6] Greg Glenn; [b6] Haynes, Barton; [b6] Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); [b6] USARMY MEDCOM WRAIR (USA); Offit, Paul; [b6] Seals, Jonathan (OS/ASPR/BARDA); [b6]
[b6] Tal Zaks
Optional Attendees: Tolman, Brett; [b6] Hopps, Markay; Kozlowski, Mary (NIH/NCI) [C]; Johnson, Maureen (NIH/NCI) [E]; [b6] Jeneffer Haynes; [b6]
[b6] Austin, Sarah (NIH/NIAID) [E]; [b6] Isabel Ramsey; Parker,

Ashley (NIH/OD) [E]; Marston, Hilary (NIH/NIAID) [E]; Qashu, Felicia (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James, Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Kurilla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Paul Gillard; Hamilton, Holli (OS/ASPR/BARDA); Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA); Kathleen Neuzil; Schrag, Stephanie (CDC/DDID/NCIRD/DBD); Verani, Jennifer R. (CDC/DDID/NCIRD/DBD); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Gonzalez, Nina; Wachtel, Jonathan; Stratton, Benjamin; Anderson, Margaret; [b6] Bethany Stokes; Ann Arvin; Vivek Shinde

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Sent: 5/18/2020 7:22:01 PM
To: [b6] Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; [b6]; Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbf6108d53148f684dad333fce983de-aarvin.stan]; Beth Bell [b6] Cavaleri Marco [b6] [b6] [b6] Greg Glenn [b6] Haynes, Barton [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d4a05845b5b4069ad0447fb60ebfa79-hayne002.mc]; [b6] [b6] Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; [b6] USARMY MEDCOM WRAIR (USA) [b6]; Offit, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbd9cc56fdb4598a57b423d484dc9f-offit.email]; [b6] Seals, Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a87d49ccb4e3caaf5eb5d3586b1cc-Jonathan.Se]; [b6] Tal Zaks [b6]
CC: Tolman, Brett [btolman@deloitte.com]; [b6] Hopps, Markay [b6] Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; Johnson, Maureen (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr]; [b6]; Jeneffer Haynes [b6] [b6]; Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; [b6] Isabel Ramsey; [b6] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [b6]; Hughes, Eric [b6] Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John

[b6]; Paul Gillard; [b6]; Hamilton, Holli (OS/ASPR/BARDA)
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=a28fc2f8eb134b00b5eaa4222d0576cc-Holli.Hamil]; [b6]
 USARMY MEDCOM WRAIR (USA); [b6]; Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange
 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33958e1252cf4266bffc8d94988f5715-kneuzil.com];
 Schrag, Stephanie (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=9be29b344ba14363bdecaa43582ca226-ZHA6]; Verani, Jennifer R.
 (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c249692151d46d6ac80cb28ada3d3a0-qzr7]; Thornburg, Natalie
 (CDC/DDID/NCIRD/DVD) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=c8d079e00a5649639c6f1425f3bb075f-nax3]; Gonzalez, Nina
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
 Wachtel, Jonathan [jwachtel@DELOITTE.com]; Stratton, Benjamin [bstratton@DELOITTE.com]; Anderson, Margaret
 [marganderson@deloitte.com]; [b6] Bethany Stokes
 [b6]

Subject: ACTIV Vaccines Working Group meeting

Location: [b6]

Start: 6/9/2020 4:30:00 PM

End: 6/9/2020 5:30:00 PM

Show Time As: Tentative

Required Attendees: [b6] Lowy, Douglas (NIH/NCI) [E]; [b6] Arvin, Ann; Beth Bell
 [b6]; Cavaleri Marco; [b6]
 [b6] Greg Glenn; [b6] Haynes,
 Barton; [b6] Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E];
 Messonnier, Nancy (CDC/DDID/NCIRD/OD); [b6] USARMY MEDCOM WRAIR (USA); Offit, Paul;
 [b6] Seals, Jonathan (OS/ASPR/BARDA); [b6] Tal Zaks
Optional Attendees: Tolman, Brett; [b6] Hopps, Markay; Kozlowski, Mary (NIH/NCI) [C]; Johnson, Maureen
 (NIH/NCI) [E]; [b6] Jeneffer Haynes; [b6]
 [b6] Austin, Sarah (NIH/NIAID) [E]; [b6]; Isabel Ramsey; Parker,
 Ashley (NIH/OD) [E]; Marston, Hilary (NIH/NIAID) [E]; Qashu, Felicia (NIH/OD) [E]; Wholley, David (FNIH) [T];
 Melencio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James,
 Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Kurilla, Michael (NIH/NCATS)
 [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Paul Gillard; Hamilton, Holli (OS/ASPR/BARDA); [b6]
 USARMY MEDCOM WRAIR (USA); Kathleen Neuzil; Schrag, Stephanie (CDC/DDID/NCIRD/DBD); Verani, Jennifer R.
 (CDC/DDID/NCIRD/DBD); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Gonzalez, Nina; Wachtel, Jonathan; Stratton,
 Benjamin; Anderson, Margaret; [b6] Bethany Stokes

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From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
Sent: 5/18/2020 7:22:02 PM
To: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Kathrin.Jansen@pfizer.com; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; [b6] Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbf6108d53148f684dad333fce983de-aarvin.stan]; Beth Bell [b6] Cavaleri Marco [b6] [b6] [b6] Haynes, Barton [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d4a05845b5b4069ad0447fb60ebfa79-hayne002.mc]; [b6] [b6] Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Nelson Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c3323ab6a02468689fa2c51a87c43cc-NelsonMicha]; Offit, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cdb9cc56fdb4598a57b423d484dcf9f-offit.email]; [b6] Seals, Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a87d49ccb4e3caaf5eb5d3586b1cc-Jonathan.Se]; [b6] Tal Zaks [b6] [b6] [b6] Hopps, Markay [b6] [b6] Tolman, Brett [b6] [b6] Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; Johnson, Maureen (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr]; [b6] Jeneffer Haynes [b6] [b6] Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; [b6] Isabel Ramsey [b6] [b6] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffb9ae95d631116f3-marstonhd]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh];

(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [b6]; Hughes, Eric [b6]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [b6]; Paul Gillard [b6] Hamilton, Holli (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a28fc2f8eb134b00b5eaa4222d0576cc-Holli.Hamil]; [b6] USARMY MEDCOM WRAIR (USA) [b6] Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33958e1252cf4266bffc8d94988f5715-kneuzil.com]; Schrag, Stephanie (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9be29b344ba14363bdecaa43582ca226-ZHA6]; Verani, Jennifer R. (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c249692151d46d6ac80cb28ada3d3a0-qzr7]; Thornburg, Natalie (CDC/DDID/NCIRD/DVD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c8d079e00a5649639c6f1425f3bb075f-nax3]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Wachtel, Jonathan [jwachtel@DELOITTE.com]; Stratton, Benjamin [bstratton@DELOITTE.com]; Anderson, Margaret [marganderson@deloitte.com]; [b6] Bethany Stokes [b6]; Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001a98d300d14b20b18c01181eb843e0-Arvinam.Sta]

Subject: Canceled: ACTIV Vaccines Working Group meeting

Location: [b6]

Start: 6/9/2020 4:00:00 AM

End: 6/10/2020 4:00:00 AM

Show Time As: Free

Required Attendees: [b6] Lowy, Douglas (NIH/NCI) [E]; [b6] Arvin, Ann; Beth Bell [b6] Cavaleri Marco; [b6]

[b6]; Haynes, [b6] Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); [b6] CIV USARMY MEDCOM WRAIR (USA); Offit, Paul;

Optional Attendees: [b6] Seals, Jonathan (OS/ASPR/BARDA); [b6] Tal Zaks Tolman, Brett; [b6] Hopps, Markay; Kozlowski, Mary (NIH/NCI) [C]; Johnson, Maureen (NIH/NCI) [E]; [b6] Jeneffer Haynes; [b6]

[b6] Austin, Sarah (NIH/NIAID) [E]; [b6] Isabel Ramsey; Parker, Ashley (NIH/OD) [E]; Marston, Hilary (NIH/NIAID) [E]; Qashu, Felicia (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James, Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Kurilla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Paul Gillard; Hamilton, Holli (OS/ASPR/BARDA); [b6] CIV USARMY MEDCOM WRAIR (USA); Kathleen Neuzil; Schrag, Stephanie (CDC/DDID/NCIRD/DBD); Verani, Jennifer R. (CDC/DDID/NCIRD/DBD); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Gonzalez, Nina; Wachtel, Jonathan; Stratton, Benjamin; Anderson, Margaret; [b6] Bethany Stokes; Ann Arvin

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 5/18/2020 8:31:14 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [b6]; Dolsten, Mikael [b6]; Fauci, Anthony (NIH/NIAID) [E] [b6]; Gibbons, Gary (NIH/NHLBI) [E] [b6]; Pao, William [b6]; Stoffels, Paul [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Colvis, Christine (NIH/NCATS) [E] [b6]; Desrosiers, Betsy [b6]; Hughes, Eric [b6]; Jansen, Kathrin [b6]; Kurilla, Michael (NIH/NCATS) [E] [b6]; Lowy, Douglas (NCI) [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Young, John [b6]; Freire, Maria (FNIH) [T] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [b6]; Disbrow, Gary (OS/ASPR/BARDA) [b6]; Marks, Peter (FDA/CBER) [b6]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]
CC: Adam, Stacey (FNIH) [T] [b6]; Alvarez, Rosa [rosalvarez@deloitte.com]; Anderson, Margaret [marganderson@deloitte.com]; Elsaid, Olivia [oelsaid@deloitte.com]; Gonzalez, Nina [ningonzalez@deloitte.com]; James, Stephanie (FNIH) [T] [b6]; Kim, Elizabeth [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]; Stratton, Ben [bstratton@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Tountas, Karen (FNIH) [T] [b6]; Wachtel, Jonathan [jwachtel@deloitte.com]; Barasch, Kimberly (NIH/NIAID) [C] [b6]; Conrad, Patricia (NIH/NIAID) [E] [b6]; Dimishkov, Roxanne (NIH/NHLBI) [C] [b6]; McManus, Ayanna (NIH/OD) [E] [b6]; Protasiewicz, Ann [b6]; Thomas, Ashley (FDA/CDER) [Ashley.Thomas@fda.hhs.gov]; Wood, Gretchen (NIH/OD) [E] [b6]; Zanellato, Ann [b6]; Burrus-Shaw, Cyndi (NIH/OD) [E] [b6]; Simon, Dina (NIH/OD) [C] [b6]; Li, Rose [b6]; FNIH Central Account [FNIH@rosellassociates.com]; Awwad, David (NIH/NIAID) [C] [b6]; Zottoli, Jessica [b6]; Togashi, Mieko (NIH/NCI) [E] [b6]; Sepulveda, Dorina (FNIH) [T] [b6]; Hardesty, Rebecca (NIH/OD) [C] [b6]; Lagos, Enrique (NIH/NCATS) [E] [b6]; Carver, Trea (NIH) [C] [b6]; Lowy, Douglas (NIH/NCI) [E] [b6]

Subject: ACTIV Executive Committee Teleconference

Location: [b6]

Start: 5/20/2020 7:30:00 PM

End: 5/20/2020 9:00:00 PM

Show Time As: Busy

Required Attendees: Collins, Francis (NIH/OD) [E]; Dolsten, Mikael; Fauci, Anthony (NIH/NIAID) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Pao, William; Stoffels, Paul; Woodcock, Janet (FDA/CDER); Tabak, Lawrence (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Freire, Maria (FNIH) [T]; Wolinetz, Carrie (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]; Anderson, James (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Marks, Peter (FDA/CBER)

Optional Attendees: Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Elsaid, Olivia; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Kim, Elizabeth; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Protasiewicz, Ann; Thomas, Ashley (FDA/CDER); Wood,

Gretchen (NIH/OD) [E]; Zanellato, Ann; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Li, Rose; FNIH Central Account; Awwad, David (NIH/NIAID) [C]; Zottoli, Jessica; Togashi, Mieko (NIH/NCI) [E]; Sepulveda, Dorina (FNIH) [T]; Hardesty, Rebecca (NIH/OD) [C]; Lagos, Enrique (NIH/NCATS) [E]; Carver, Trea (NIH) [C]; Lowy, Douglas (NIH/NCI) [E]; **b6**

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Subject: ACTIV Response Partnership Leadership Team Meeting #4
Location: [b6]
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Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Collins, Francis (NIH/OD) [E]; Corey, Larry; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbelding, Emily (NIH/NIAID) [E]; Fauci, Anthony (NIH/NIAID) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Pangalos, Mene; Pao, William; Paul, Steve; Perlmutter, Roger; Plump, Andy; Rasi, Guido; Reed, John; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Tsai, John; Vessey, Rupert; Virgin, Skip; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Freire, Maria (FNIH) [T]; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Gonzalez, Nina; Kim, Elizabeth; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Rachel Ramoni; Plenge, Robert; Talley, Michael; **b6**; Cavaleri, Marco; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Gibbons, Gary (NIH/NHLBI) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]

Optional Attendees: Barasch, Kimberly (NIH/NIAID) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Conrad, Patricia (NIH/NIAID) [E]; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Lagos, Enrique (NIH/NCATS) [E]; McManus, Ayanna (NIH/OD) [E]; Melencio, Cheryl (FNIH) [T]; Protasiewicz, Ann; Simon, Dina (NIH/OD) [C]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Sepulveda, Dorina (FNIH) [T]; FNIH Central Account; Li, Rose; Zottoli, Jessica; Parker, Ashley (NIH/OD) [E]; Gladman, Jordan (NIH/OD) [E]; Elsaid, Olivia; Castillejos zenteno, Carlos [JRDUS]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Burklow, John (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Hallett, Adrienne (NIH/OD) [E]; Chen, Helen; Lowy, Douglas (NIH/NCI) [E]; Meltzer, Abbey (FNIH) [T]; Gorman, Greta (FNIH) [T]; Dana Carluccio

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To: Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Sandeep Menon [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price [b6]; [b6] Eron, Joe [b6]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; [b6] Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]
CC: Demarcus [b6] Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa [b6]; Eron, Joseph J Jr [b6] Smith, David [b6]; Paul Klekotka [b6]; Ajay Nirula [b6]
Subject: Follow-up from ACTIV TX-Clinical Master Protocol Outpatient mAbs Writing Team Meeting #1
Attachments: a5401-d03-activ-051620.docx; ACTIV_Therapeutics-Clinical_MP Sub-Group Meeting 18May2020_Key Takeaways.pdf

Dear ACTIV Outpatient mAbs Writing Team,

Please find attached the notes from today's meeting that Elizabeth did a great job in capturing. While I know we would have liked to make more forward headway, I do think our conversations put us on the right path to take the next step forward.

Per the action items:

- Karen and Lisa are going to discuss the statistical parameters and they are going to try and capture that is a summary for the synopsis that we need for Wednesday's meeting with the Steering Committee that includes Janet Woodcock and others who will want to weigh in.
- Ajay and Paul were going to work on getting some of the Lilly data together to help us determine if we should have two primary endpoints: one virologic and one symptomatic. Or whether we are safer leaving the virologic endpoint as secondary as it is currently written.
- We are going to try to work up minimal entry criteria for mAbs entering the study. We discussed tox and Phase 1 data, [b5] testing with a minimum level of effect (though we aren't sure what the minimum should be, could use some counsel). **If the group has additional thoughts for these criteria please send them to me and I will compile.**

In addition, we wanted to set another meeting of these team for tomorrow. I have discussed with Karen and Lisa and they think they could have some thoughts together for the group's response by 4pm tomorrow. **Would this group be able to meet from 4-5pm ET tomorrow?**

Finally, the ACTG team that has been working on the base protocol would like to hear any other feedback not covered in the action items above from the group, so if you all can review and be ready to provide thoughts or send them in redline and comments ahead of the meeting, that would be perfect. (Document attached once again for ease of reference.)

Once again, thank you all for being willing to come together and get this protocol revised to fit the capacity needs of this new venture!

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
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CC: Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Kenny, Dermot [b6]; Weinmann, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang]; Garner, Carlos [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [b6]; Jansen, Kathrin [b6]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [b6]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [marganderson@deloitte.com]; Carluccio, Dana [b6]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny [b6]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [b6]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a27ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveson, Nancy [b6]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Criffield, Robin [b6]; Hamilton, Nancy [b6]; Minnich, Beth [b6]; Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Stratton, Benjamin [bstratton@DELOITTE.com]; Tolman, Brett [btolman@deloitte.com]; Victoria Davey [/o=ExchangeLabs/ou=Exchange

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Jintanat Ananworanich [b6]

Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting
Attachments: Clinical Trial Capacity Working Group Meeting Agenda_05192020.pdf
Location: [b6]

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Optional Attendees: Sizemore, Christine (NIH/FIC) [E]; Kenny, Dermot; Weinmann, Gail (NIH/NHLBI) [E]; Garner, Carlos; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Carluccio, Dana; Cheryl (FNIH) Melencio [T] [b6]; Francis Collins; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH); Tuveson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Minnich, Beth; Rebecca (NIH/NCATS) Katz [E] [b6]; Stratton, Benjamin; Tolman, Brett; Davey, Victoria; Jintanat Ananworanich

Dear Colleagues, We have an interesting agenda (attached) for this call and look forward to the discussion surrounding each topic! Best, Karen

ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines

Dear Clinical Trial Capacity Working Group members,

In anticipation of this working group making rapid progress on identified action items and other activities, the co-chairs have agreed that it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify areas of need, and to determine next steps. We ask that you make every effort possible to join each of these meetings, but understand that at times you may have competing priorities. To place a hold on your calendar, please accept this meeting invite with a response; later you can decline an individual meeting if you have a conflict.

An agenda and other meeting materials, as needed, will be distributed prior to each call.

With best regards,
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health

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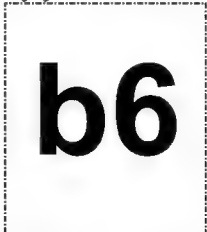
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From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]

Sent: 5/19/2020 1:17:11 AM

To: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Bascles, Lionel [b6]; Cohen, Myron [b6]; Corey, Larry [b6]; Desrosiers, Betsy [b6]; Dickens, Jim (NIH/NCATS) [C] [b6]; Doroshov, James (NIH/NCI) [E] [b6]; Goff, David (NIH/NHLBI) [E] [b6]; Kurilla, Michael (NIH/NCATS) [E] [b6]; Nayak, Seema (NIH/NIAID) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Payton, Manizhe (NIH/NIAID) [E] [b6]; Resnansky, Laura [b6]; Srinivasan, Badhri [b6]; Wachtel, Jonathan [jwachtel@deloitte.com]; Qashu, Felicia (NIH/OD) [E] [b6]; Vincent, Mike [b6]; Stein, Peter (FDA/CDER) [b6]

CC: Colvis, Christine (NIH/NCATS) [E] [b6]; Jansen, Kathrin [b6]; Lowy, Douglas (NCI) [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Young, John [b6]; Adam, Stacey (FNIH) [T] [b6]; Anderson, Margaret [marganderson@deloitte.com]; Carluccio, Dana [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Gonzalez, Nina [ningonzalez@deloitte.com]; Heaton, Penny [b6]; James, Stephanie (FNIH) [T] [b6]; Li, Rose [b6]; Menetski, Joseph (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]; Tuveson, Nancy [b6]; Wholley, David (FNIH) [T] [b6]; Criffield, Robin [b6]; Minnich, Beth [b6]; Katz, Rebecca (NIH/NCATS) [E] [b6]; Stratton, Benjamin [bstratton@DELOITTE.com]; Tolman, Brett [btolman@deloitte.com]; Victoria Davey [b6]; Jintanat Ananworanich [b6]; Sizemore, Christine (NIH/FIC) [E] [b6]; Kenny, Dermot [b6]; Weinmann, Gail (NIH/NHLBI) [E] [b6]; Garner, Carlos [b6]; Hughes, Eric [b6]; Hamilton, Nancy [b6]

Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting

Attachments: Clinical Trial Capacity Working Group Meeting Agenda_05192020.pdf

Location: [b6]

Start: 5/19/2020 1:00:00 PM

End: 5/19/2020 2:00:00 PM

Show Time As: Tentative

Recurrence: Weekly
every Tuesday and Friday from 9:00 AM to 10:00 AM

Required Attendees: Vincent, Mike; Stein, Peter (FDA/CDER); Bascles, Lionel; Cohen, Myron; Corey, Larry; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshov, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; Kurilla, Mike; Nayak, Seema (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Payton, Manzine; Resnansky, Laura; Srinivasan, Badhri; Wachtel, Jonathan; Qashu, Felicia

Optional Attendees: Sizemore, Christine (NIH/FIC) [E]; Kenny, Dermot; Weinmann, Gail (NIH/NHLBI) [E]; Garner, Carlos; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Carluccio, Dana; Cheryl (FNIH) Melencio [T] [b6]; Francis Collins; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH); Tuveson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Minnich, Beth; Rebecca (NIH/NCATS) Katz [E] [b6]; Stratton, Benjamin; Tolman, Brett; Davey, Victoria; Jintanat Ananworanich

Dear Colleagues, We have an interesting agenda (attached) for this call and look forward to the discussion surrounding each topic! Best, Karen

ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines

LTAB0000007307

Dear Clinical Trial Capacity Working Group members,

In anticipation of this working group making rapid progress on identified action items and other activities, the co-chairs have agreed that it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify areas of need, and to determine next steps. We ask that you make every effort possible to join each of these meetings, but understand that at times you may have competing priorities. To place a hold on your calendar, please accept this meeting invite with a response; later you can decline an individual meeting if you have a conflict.

An agenda and other meeting materials, as needed, will be distributed prior to each call.

With best regards,
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/19/2020 2:23:05 AM
To: Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [b6]; Keith Gottesdiener [b6]; Elliott Levy [b6]; Wung, Peter /US [b6]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [b6]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bafd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Rose Li Central Account [FNIH@roseliassociates.com]
Subject: ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #11
Attachments: Therapeutic information request form-v9-clean.docx; ACTIV_Therapeutics Clinical Agent Prioritization Sub Group_19May2020 Meeting Guide.pdf
Location: [b6]
Start: 5/19/2020 5:00:00 PM
End: 5/19/2020 6:00:00 PM
Show Time As: Tentative

Required Attendees: Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E]
Optional Attendees: Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; [b6]; Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E]; [b6]; Rose Li Central Account

Dear ACTIV TX-Clinical Agent Prioritization Subgroup,

Please find attached the materials for tomorrow's call.

1. Slides with topics and agenda internal.
2. Updated Company RFI/Survey for final review.

Thanks,
Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/19/2020 2:23:07 AM
To: Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [b6]; Keith Gottesdiener [b6]; Elliott Levy [b6]; Wung, Peter /US [b6]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [b6]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Rose Li Central Account [FNIH@roseliassociates.com]
Subject: Materials for ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #11
Attachments: ACTIV_Therapeutics Clinical Agent Prioritization Sub Group_19May2020 Meeting Guide.pdf; Therapeutic information request form-v9-clean.docx

Dear ACTIV TX-Clinical Agent Prioritization Subgroup,

Please find attached the materials for tomorrow's call.

1. Slides with topics and agenda internal.
2. Updated Company RFI/Survey for final review.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/19/2020 2:32:19 AM
To: Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [b6] LaVange, Lisa M [b6] Sandeep Menon [b6] Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price [b6] Eron, Joe [b6] Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; [b6] Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]
CC: Demarcus [b6] Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa [b6] Eron, Joseph J Jr [b6] Smith, David Paul Klekotka [b6] Ajay Nirula [b6]
Subject: HOLD for Potential: ACTIV TX-Clinical Neutralizing mAb Outpatient MP Writing Team Meeting
Location: [b6]
Start: 5/19/2020 8:00:00 PM
End: 5/19/2020 9:30:00 PM
Show Time As: Tentative

Required Attendees: Judy Currier; Eric Hughes; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; [b6] Eron, Joe; Javan, Arzhang (NIH/NIAID) [E]; Roa, Jhoanna; [b6] Kim, Peter (NIH/NIAID) [E]
Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Jhoanna Roa; Eron, Joseph J Jr; Smith, David; Paul Klekotka; Ajay Nirula

Dear ACTIV-2 Writing Team,

Please save this time if you can for our next writing team meeting. While I am still waiting on a few critical confirmations since majority can make it, I want to go ahead and block it off.

An agenda will be send once we have the necessary participants confirmed.

Thanks,

Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
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To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Judy Currier
[b6]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Sandeep Menon [b6]; Proschan, Michael (NIH/NIAID) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Price, Dionne (FDA/CDER) [b6]; Rubin, Daniel B. (FDA/CDER) [b6]; Farley, John (FDA/CDER) [b6]; Karen Lynn Price [b6]; Eron, Joe [b6]; Javan, Arzhang (NIH/NIAID) [E] [b6]; Roa, Jhoanna [b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Jonathan Li [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]; Demarcus [b6]; Tountas, Karen (FNIH) [T] [b6]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jhoanna Roa [b6]; Eron, Joseph J Jr [b6]; Smith, David [b6]; Paul Klekotka [b6]; Ajay Nirula [b6]; Elsaid, Olivia [oelsaid@deloitte.com]; Robert Jan Benschop [b6]; Lei Shen [b6]

CC: Demarcus [b6]; Tountas, Karen (FNIH) [T] [b6]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jhoanna Roa [b6]; Eron, Joseph J Jr [b6]; Smith, David [b6]; Paul Klekotka [b6]; Ajay Nirula [b6]; Elsaid, Olivia [oelsaid@deloitte.com]; Robert Jan Benschop [b6]; Lei Shen [b6]

Subject: Confirmed: ACTIV TX-Clinical Neutralizing mAb Outpatient MP Writing Team Meeting
Attachments: ACTIV Therapeutics-Clinical mAb outpatient MP 19May2020 Agenda.pdf
Location: [b6]

Start: 5/19/2020 8:00:00 PM
End: 5/19/2020 9:30:00 PM
Show Time As: Busy

Required Attendees: Adam, Stacey (FNIH) [T]; Judy Currier; Eric Hughes; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; [b6]; Joe; Javan, Arzhang (NIH/NIAID) [E]; Roa, Jhoanna; [b6]; Kim, Peter (NIH/NIAID) [E]; Jonathan Li; Marks, Gilbert (OS/ASPR/BARDA) (CTR)

Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Jhoanna Roa; Eron, Joseph J Jr; Smith, David; Paul Klekotka; Ajay Nirula; Elsaid, Olivia; Robert Jan Benschop; Lei Shen

Dear ACTIV-2 Writing Team,

This meeting is now confirmed. We should have quorum with people coming a little late or leaving a little early, but with the necessary overlap.

Please see the suggested attached agenda. Please let me know if you have additions or amendments.

Thanks,

Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/19/2020 2:32:20 AM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Judy Currier [b6]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Sandeep Menon [b6]; Proschan, Michael (NIH/NIAID) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Price, Dionne (FDA/CDER) [b6]; Rubin, Daniel B. (FDA/CDER) [b6]; Farley, John (FDA/CDER) [b6]; Karen Lynn Price [b6]; Eron, Joe [b6]; Javan, Arzhang (NIH/NIAID) [E] [b6]; Roa, Jhoanna [b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Jonathan Li [b6]; Demarcus [b6]; Tountas, Karen (FNIH) [T] [b6]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jhoanna Roa [b6]; Eron, Joseph J Jr [b6]; Smith, David [b6]; Paul Klekotka [b6]; Ajay Nirula [b6]

CC:

Subject: HOLD for Potential: ACTIV TX-Clinical Neutralizing mAb Outpatient MP Writing Team Meeting
Location: [b6]

Start: 5/19/2020 8:00:00 PM
End: 5/19/2020 9:30:00 PM
Show Time As: Busy

Required Attendees: Judy Currier; Eric Hughes; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; [b6]; Eron, Joe; Javan, Arzhang (NIH/NIAID) [E]; Roa, Jhoanna; [b6]; Kim, Peter (NIH/NIAID) [E]; Jonathan Li [b6]

Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Jhoanna Roa; Eron, Joseph J Jr; Smith, David; Paul Klekotka; Ajay Nirula

Dear ACTIV-2 Writing Team,

Please save this time if you can for our next writing team meeting. While I am still waiting on a few critical confirmations since majority can make it, I want to go ahead and block it off.

An agenda will be send once we have the necessary participants confirmed.

Thanks,

Stacey

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From: Young, John [b6]
Sent: 5/19/2020 12:06:52 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
CC: Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Carlos O Garner [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Elizabeth Kim [elkim@deloitte.com]; Elliott Levy [b6]; Eric Hughes [b6]; [b6] Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; [b6] Keith Gottesdiener [b6]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Lucas Smalldon [b6]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Naimish Patel [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Poole, Mike [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Rose Li Central Account [FNIH@roseliassociates.com]; Ruxandra Draghia-Akli [b6]; Salathin, Carla [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Vincent, Michael [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Wung, Peter /US [b6]
Subject: Re: ACTIV 1X-Clinical Agent Prioritization Subgroup Meeting #11

Hi Stacey

Thanks for sharing the materials. Some additional points of consideration for the SARS-CoV-2 neutralizing antibodies:

b4

Best regards

John

On Tue, 19 May 2020 at 04:24, Adam, Stacey (FNIH) [T] [b6] wrote:

APAR0000005375

Dear ACTIV TX-Clinical Agent Prioritization Subgroup,

Please find attached the materials for tomorrow's call.

1. Slides with topics and agenda internal.
2. Updated Company RFI/Survey for final review.

Thanks,

Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
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[b6]
[b6] Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; [b6] Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Jonathan Li [b6]
CC: Demarcus [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jhoanna Roa [b6] Eron, Joseph J Jr [b6] Smith, David [b6] Paul Klekotka [b6] Ajay Nirula [b6]
Subject: Confirmed: ACTIV TX-Clinical Neutralizing mAb Outpatient MP Writing Team Meeting
Attachments: ACTIV Therapeutics-Clinical mAb outpatient MP 19May2020 Agenda.pdf
Location: [b6]
Start: 5/19/2020 8:00:00 PM
End: 5/19/2020 9:30:00 PM
Show Time As: Tentative

Required Attendees: Judy Currier; Eric Hughes; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; [b6]
[b6]; Eron, Joe; Javan, Arzhang (NIH/NIAID) [E]; Roa, Jhoanna; [b6] Kim, Peter (NIH/NIAID) [E]; Jonathan Li
Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Jhoanna Roa; Eron, Joseph J Jr; Smith, David; Paul Klekotka; Ajay Nirula

Dear ACTIV-2 Writing Team,

This meeting is now confirmed. We should have quorum with people coming a little late or leaving a little early, but with the necessary overlap.

APAR0000005372-2443012

Please see the suggested attached agenda. Please let me know if you have additions or amendments.

Thanks,

Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
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CC: Demarcus [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa [b6]; Eron, Joseph J Jr [b6]; Smith, David [b6]; Paul Klekotka [b6]; Ajay Nirula [b6]; Elsaid, Olivia [oelsaid@deloitte.com]
Subject: RE: Confirmed: ACTIV TX-Clinical Neutralizing mAb Outpatient MP Writing Team Meeting
Attachments: ACTIV Therapeutics-Clinical mAb outpatient MP 19May2020 Agenda.pdf; a5401-d03-activ-051620_Lilly_Paul_Klekotka.docx

Dear ACTIV-2 Writing Team,

Please see the suggested attached agenda.

In addition, I am circulating a draft of the protocol with some comments from our Lilly colleagues. Looking forward to seeing you all in about an hour.

Thanks,

Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
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CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Rose Li Central Account [b6]
Subject: Initial Follow-up to ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #11
Attachments: ACTIV_Therapeutics-Clinical_AP Sub-Group Meeting 19May2020_Key Takeaways.pdf

Dear ACTIV TX-Clinical Agent Prioritization Subgroup,

Thank you all for a productive meeting today. I am glad we were able to finalize the RFI/Survey for the companies. We are well into building the REDCap data capture platform. We will share with you all the link once it is done.

Thank you as well for your feedback on the mAbs. Many of you have already gotten back to me with nominations for the committee, so I will like follow up individually with those who have expressed interest and if we do not fully meet our 6-8, I will then reach out again to the broader group.

For your reference, please find attached the high level notes for the meeting. The formal complete summary will be sent tomorrow.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer

APAR0000005367

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[b6] Eron, Joe [b6] Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; [b6] Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Jonathan Li [b6] Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]
CC: Demarcus [b6] Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa [b6] Eron, Joseph J Jr [b6] Smith, David Paul Klekotka [b6] Ajay Nirula [b6] Elsaid, Olivia [oelsaid@deloitte.com]; Robert Jan Benschop [benschop_robert@lilly.com]; Lei Shen [b6]
Subject: Follow-up from ACTIV TX-Clinical Neutralizing mAb Outpatient MP Writing Team Meeting
Attachments: ACTIV_Therapeutics-Clinical_ACTIV TX-Clinical Neutralizing mAb Outpatient MP 19May2020_Key Takeaways.pdf; ACTIV_200519.pdf; ACTIV2_MasterProtocolWritingMeeting_May19_LisaKaren_Final.pdf; 5401 Protocol Synopsis 051920v2.docx

Dear ACTIV TX-Clinical mAb Outpatient WT,

Thank you all for a very productive meeting today. I think we covered a lot of group, and while I know we still have a lot more to cover, we made some progress!

I am attaching the notes that our Deloitte colleague Olivia was kind enough to capture for us, and I have attached both Lisa and Karen's and Michael's slide set for the group's reference. Please let me know if you have questions on any of these.

In addition, I am attaching a protocol synopsis that the ACTG team was kind enough to draft up to space me splicing together slides tomorrow for the presentation to the ACTIV mAb Master Protocol Steering Committee who will meet to review tomorrow.

For this group, I would like to get our next meeting on the books. **Time may be tight tomorrow due to a number of other meetings. Does the group want to shoot for an evening call, starting around 5:30 or 6pm ET?** Please let me know what might work for you and I will see if we can get quorum.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Foundation for the National Institutes of Health

Direct: [b6] Mobile: [b6]

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From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 5/20/2020 1:14:55 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskip]; [b6]
[b6]
[b6] Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; [b6]
[b6]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; [b6]
[b6] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; [b6]
[b6] Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [b6]
[b6] Hughes, Eric [b6]; Jansen, Kathrin [b6]
[b6] Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4b79577e2aa8d1-jamesst]; Kim, Elizabeth [elkim@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Wachtel, Jonathan [jwachtel@DELOITTE.com]; Prabhavathi Fernandes [b6]; Diamond, Michael [b6]; Rose Li [b6]
[b6] Dana Carluccio [b6]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [b6]
[b6] Dave Frankowski [b6]
Subject: RE: ACTIV Preclinical working group (Friday meeting)

Attachments: PRECLINICAL_Working Group_Agenda_0520_d1.pptx; ACTIV PRECLINICAL_Animal Model Inventory_20200514
jpm.xlsx

Hi all,

Please find attached some materials to aid in our discussion today. The first document contains the agenda as well as our WG's objectives and timeline. Also attached is the Animal Model Inventory.

Please let us know if you have any questions.

Best,

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T] b6
Sent: Tuesday, April 14, 2020 6:49 PM
To: Menetski, Joseph (FNIH) [T]; b6
b6
b6 Baric, Ralph; b6 Ottinger, Elizabeth
(NIH/NCATS) [E]; COVITS, CHRISTINE (NIH/NCATS) [E]; Hewitt, JUDITH (NIH/NIAID) [E]; Deming, Damon
(FDA/CDER); b6 Parker, Ashley (NIH/OD)
[E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA)
Cc: Wholley, David (FNIH) [T]; Austin, christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T];
Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI);
Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH)
[T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan;
Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson,
Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E];
Rodriguez, Robin D; Dave Frankowski
Subject: ACTIV Preclinical working group (Friday meeting)
When: Friday, May 22, 2020 11:00 AM-12:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: b6

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/20/2020 4:02:38 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Karen Lynn Price [b6] Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Carlos O Garner [b6]
CC: Demarcus [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: ACTIV TX-Clinical Master Protocol mAbs Steering Committee - ACTIV2 Synopsis Review
Attachments: 5401 Protocol Synopsis 051920v3.docx
Location: [b6]
Start: 5/20/2020 5:00:00 PM
End: 5/20/2020 6:00:00 PM
Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Judy Currier; Eric Hughes; Lisa LaVange; Read, Sarah (NIH/NIAID) [E]; Karen Lynn Price; Higgs, Elizabeth (NIH/NIAID) [E]; Woodcock, Janet (FDA/CDER); Stein, Peter (FDA/CDER); Carlos O Garner
Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]

Dear ACTIV TX-Clinical Master Protocol mAbs Steering Committee,

Please find attached the synopsis of the outpatient protocol for review at our meeting today. This was assembled by the ACTG group based on our writing team conversations and then edited a bit by Lisa and Karen for the statistical sections.

This document is NOT ready to share beyond this group yet, but could be gotten ready in short turn if needed for the company summit, Janet. We will just need to know when that is.

Finally, we will be discussing the selection of the inpatient network for the companion protocol today.

Thanks,

Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/20/2020 6:16:30 PM
To: Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Sandeep Menon [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price [b6]; Eron, Joe [b6]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; [b6] Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Jonathan Li [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]
CC: Demarcus [b6] Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa [b6]; Eron, Joseph J Jr [b6]; Smith, David [b6]; Paul Klekotka [b6]; Ajay Nirula [b6]; Elsaid, Olivia [oelsaid@deloitte.com]; Robert Jan Benschop [b6]; Lei Shen [b6]
Subject: RE: Follow-up from ACTIV TX-Clinical Neutralizing mAb Outpatient MP Writing Team Meeting

Dear ACTIV TX-Clinical mAb Outpatient WT,

It looks like we can get about ¾ of the group together tonight. Would the group still like to meet from 6-7pm ET.

In the thought that I think we will want to, I am going to send a calendar hold with a zoom link just in case.

Thanks,
STacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [b6] Mobile: [b6]

From: Adam, Stacey (FNIH) [T]
Sent: Tuesday, May 19, 2020 11:05 PM
Subject: Follow-up from ACTIV TX-Clinical Neutralizing mAb Outpatient MP Writing Team Meeting

APAR0000005359

Dear ACTIV TX-Clinical mAb Outpatient WT,

Thank you all for a very productive meeting today. I think we covered a lot of group, and while I know we still have a lot more to cover, we made some progress!

I am attaching the notes that our Deloitte colleague Olivia was kind enough to capture for us, and I have attached both Lisa and Karen's and Michael's slide set for the group's reference. Please let me know if you have questions on any of these.

In addition, I am attaching a protocol synopsis that the ACTG team was kind enough to draft up to space me splicing together slides tomorrow for the presentation to the ACTIV mAb Master Protocol Steering Committee who will meet to review tomorrow.

For this group, I would like to get our next meeting on the books. **Time may be tight tomorrow due to a number of other meetings. Does the group want to shoot for an evening call, starting around 5:30 or 6pm ET?** Please let me know what might work for you and I will see if we can get quorum.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
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To: Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [b6] LaVange, Lisa M [b6]; Sandeep Menon [b6] Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price [b6]
[b6] Eron, Joe [b6] Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; [b6] Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Jonathan Li [b6] Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eedb7-Gilbert.Mar]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]
CC: Demarcus [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa [b6] Eron, Joseph J Jr [b6]; Smith, David [b6] Paul Klekotka [b6]; Ajay Nirula [b6] Elsaid, Olivia [oelsaid@deloitte.com]; Robert Jan Benschop [b6] Lei Shen [b6]
Subject: HOLD for ACTIV TX-Clinical mAb Outpatient WT Meeting-3
Location: [b6]
Start: 5/20/2020 10:00:00 PM
End: 5/20/2020 11:00:00 PM
Show Time As: Tentative

Required Attendees: Judy Currier; Eric Hughes; LaVange, Lisa M; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; [b6]
[b6] Javan, Arzhang (NIH/NIAID) [E]; Roa, Jhoanna; [b6] Kim, Peter (NIH/NIAID) [E]; Jonathan Li; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Kozak, Marina (OS/ASPR/BARDA)
Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Jhoanna Roa; Eron, Joseph J Jr; Smith, David; Paul Klekotka; Ajay Nirula; Elsaid, Olivia; Robert Jan Benschop; Lei Shen

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To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Judy Carrier
[b6]; Eric Hughes [b6]; LaVange, Lisa M [b6]
Sandeep Menon [b6]; Proschan, Michael (NIH/NIAID) [E] [b6]
Read, Sarah (NIH/NIAID) [E] [b6]; Price, Dionne (FDA/CDER) [b6]; Rubin,
Daniel B. (FDA/CDER) [b6]; Farley, John (FDA/CDER) [b6]; Karen Lynn
[b6]
[b6]; Eron, Joe
[b6]; Javan, Arzhang (NIH/NIAID) [E] [b6]; Roa, Jhoanna [b6]
LHosey@s-3.com; Kim, Peter (NIH/NIAID) [E] [b6]; Jonathan Li [b6]; Marks,
Gilbert (OS/ASPR/BARDA) (CTR) [b6]; Kozak, Marina (OS/ASPR/BARDA)
[b6]
CC: Demarcus [b6]; Tountas, Karen (FNIH) [T] [b6]; Wachtel, Jonathan
[jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa
[b6]; Eron, Joseph J Jr [b6]; Smith, David
[b6]; Paul Klekotka [b6]; Ajay Nirula [b6]; Elsaid,
Olivia [oelsaid@deloitte.com]; Robert Jan Benschop [b6]; Lei Shen [b6]
Subject: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3
Attachments: 5401 Protocol Synopsis 051920v3.docx
Location: [b6]
Start: 5/20/2020 10:00:00 PM
End: 5/20/2020 11:00:00 PM
Show Time As: Tentative

Required Attendees: Judy Carrier; Eric Hughes; LaVange, Lisa M; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price;
[b6]
[b6]; Eron, Joe; Javan, Arzhang (NIH/NIAID) [E]; Roa, Jhoanna;
[b6]; Kim, Peter (NIH/NIAID) [E]; Jonathan Li; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Kozak, Marina (OS/ASPR/BARDA)
Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Jhoanna Roa;
Eron, Joseph J Jr; Smith, David; Paul Klekotka; Ajay Nirula; Elsaid, Olivia; Robert Jan Benschop; Lei Shen

Dear mAb Outpatient WT,

It seems like we can still get quorum, so I think we should proceed with who we have.

Thanks,

Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/20/2020 9:42:26 PM
To: Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Sandeep Menon [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price [b6]; Eron, Joe [b6]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; [b6] Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Jonathan Li [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eedb7-Gilbert.Mar]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]
CC: Demarcus [demarcus@email.unc.edu]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa [b6]; Eron, Joseph J Jr [b6]; Smith, David [b6]; Paul Klekotka [b6]; Ajay Nirula [b6]; Elsaid, Olivia [oelsaid@deloitte.com]; Robert Jan Benschop [b6]; Lei Shen [b6]
Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3
Attachments: General comments from CDER FDA re ACTIV TX outpatient mAb trial 052020 (002).docx; 5401 Protocol Synopsis 051920v3.docx

Dear mAb Outpatient WT,

The FDA team that has been working with ACTIV and sitting in on our writing team meetings for this protocol would like to offer the attached thoughts for the group's consideration on tonight's call.

Also, attaching again the updated synopsis that was discussed with the mAb Steering Committee earlier today.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

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From: Carlos O Garner [REDACTED] b6
Sent: 5/20/2020 11:40:07 PM
To: Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [REDACTED] b6 LaVange, Lisa M [REDACTED] b6; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Karen Lynn Price [REDACTED] b6 Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Demarcus [REDACTED] b6 Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: Re: [EXTERNAL] Re: ACTIV TX-Clinical Master Protocol mAbs Steering Committee - ACTIV2 Synopsis Review

I support Libby's recommendation. It will be important that the lead network consider this their top priority for implementation and managing the supportive networks like PETAL. I also particularly support that NIAID hold the IND.

Regards,

Carl

From: "Higgs, Elizabeth (NIH/NIAID) [E]" [REDACTED] b6
Date: Wednesday, May 20, 2020 at 4:54 PM
To: "Adam, Stacey (FNIH) [T]" [REDACTED] b6 "Bozzette, Sam (NIH/NCATS) [E]" [REDACTED] b6
"Butterson, Joan" [REDACTED] b6 Judy Currier [REDACTED] b6, Eric Hughes [REDACTED] b6
[REDACTED] b6 "LaVange, Lisa M" [REDACTED] b6 "Read, Sarah (NIH/NIAID) [E]" [REDACTED] b6
[REDACTED] b6 Karen Lynn Price [REDACTED] b6 "Higgs, Elizabeth (NIH/NIAID) [E]" [REDACTED] b6
[REDACTED] b6 "Woodcock, Janet (FDA/CDER)" [REDACTED] b6 "Stein, Peter (FDA/CDER)" [REDACTED] b6
[REDACTED] b6 Carlos Garner [REDACTED] b6, "Bugin, Kevin (FDA/CDER)" [REDACTED] b6
[REDACTED] b6 "Marks, Gilbert (OS/ASPR/BARDA) (CTR)" [REDACTED] b6
Demarcus [REDACTED] b6 "Tountas, Karen (FNIH) [T]" [REDACTED] b6, "Wachtel, Jonathan" <jwachtel@deloitte.com>, Elizabeth Kim <elkim@deloitte.com>, "Parker, Ashley (NIH/OD) [E]" [REDACTED] b6
Subject: [EXTERNAL] Re: ACTIV TX-Clinical Master Protocol mAbs Steering Committee - ACTIV2 Synopsis Review

EXTERNAL EMAIL: Use caution before replying, clicking links, and opening attachments.

Dear ACTIV mAb SC Colleagues,

I would like to propose that INSIGHT be identified as the lead network for the inpatient mAb study, with NIAID holding the IND, with the proviso that they work collaboratively with the PETAL network, companies, our SC etc. as one protocol team. We would also want assurance that this will be their priority.

Someone commented that INSIGHT was overcommitted and I do not think this is the case, they have an 10,000 outpatient COVID observational study which can contribute enrollment to the inpatient study through early identification of COVID patients needing hospitalization, and over 300 sites globally and no interventional studies at this time though European sites are supporting ACTT 2 (though not yet). They have done a lot of thinking on their inpatient protocol for HIVIG and this could be leveraged as a started point just as we leveraged the ACTG draft protocol.

The addition of PETAL sites domestically to the domestic sites in INSIGHT would be an advantage. The addition of the entire VA Hospital system could be a huge advantage as well. With so many sites we should enroll quickly.

Finally, the INSIGHT network is already operational with an excellent track record in registrational trials. I worry a bit that the NHLBI new network of networks will take some time to stand up operationally and would prefer the USG held the IND.

Hoping I'm not biased by my NIAID origin, but I am comfortable that INSIGHT can lead this.

Thanks,

Libby

From: [b6]
When: 1:00 PM - 2:00 PM May 20, 2020
Subject: ACTIV TX-Clinical Master Protocol mAbs Steering Committee - ACTIV2 Synopsis Review
Location: [b6]

Dear ACTIV TX-Clinical Master Protocol mAbs Steering Committee,

Please find attached the synopsis of the outpatient protocol for review at our meeting today. This was assembled by the ACTG group based on our writing team conversations and then edited a bit by Lisa and Karen for the statistical sections.

This document is NOT ready to share beyond this group yet, but could be gotten ready in short turn if needed for the company summit, Janet. We will just need to know when that is.

Finally, we will be discussing the selection of the inpatient network for the companion protocol today.

Thanks,

Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/21/2020 1:50:00 AM
To: Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [b6] Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [b6]; Keith Gottesdiener [b6]; Elliott Levy [b6]; Wung, Peter /US [b6]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [b6]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Rose Li Central Account [FNIH@roseliassociates.com]
Subject: Materials for ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #12
Attachments: ACTIV_Therapeutics Clinical Agent Prioritization Sub Group_21May2020 Meeting Guide.pdf; 2020-05-19_TX-Clinical_WG_Agent_Prioritization_Committee_Meeting-Summary.pdf

Dear TX-Clinical Agent Prioritization Subgroup,

Please find attached the formal summary from yesterday's meeting.

In addition, please find the slides for tomorrow's meetings. Please let me know if you have any amendments or additions.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

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Stacey Adam is inviting you to a scheduled Zoom meeting.

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CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bafd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Rose Li Central Account [FNIH@roseliassociates.com]
Subject: ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #12
Attachments: 2020-05-19_TX-Clinical_WG_Agent_Prioritization_Committee_Meeting-Summary.pdf; ACTIV_Therapeutics Clinical Agent Prioritization Sub Group_21May2020 Meeting Guide.pdf
Location: [b6]
Start: 5/21/2020 3:00:00 PM
End: 5/21/2020 4:00:00 PM
Show Time As: Tentative

Required Attendees: Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E]
Optional Attendees: Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; [b6]; Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E]; [b6]; Rose Li Central Account

Dear TX-Clinical Agent Prioritization Subgroup,

APAR0000005338

Please find attached the formal summary from yesterday’s meeting.
In addition, please find the slides for tomorrow’s meetings. Please let me know if you have any amendments or additions.

Thanks,
Stacey

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From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
Sent: 5/21/2020 1:29:07 PM
To: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr];

[b6] Lowy, Douglas (NIH/NCI) [E] [b6]
Arvin, Ann [b6] Beth Bell [b6]
[b6] Cavaleri Marco [b6]
[b6] Greg Glenn [b6]
[b6] Haynes, Barton [b6]
Marks, Peter (FDA/CBER) [b6] Mascola, John (NIH/VRC) [E] [b6];
Messonnier, Nancy (CDC/DDID/NCIRD/OD) [b6] Michael, [b6] USARMY MEDCOM [b6]
(USA) [b6]; Offit, Paul [b6] Seals, Jonathan (OS/ASPR/BARDA)
[b6] Tal Zak [b6]
CC: Tolman, Brett [btolman@deloitte.com]; [b6] Hopps, Markay [b6]
Kozlowski, Mary (NIH/NCI) [C] [b6]; Johnson, Maureen (NIH/NCI) [E]
[b6] Jeneffer Haynes [b6]
Austin, Sarah (NIH/NIAID) [E]
[b6] Isabel Ramsey [b6] Parker,
Ashley (NIH/OD) [E] [b6] Marston, Hilary (NIH/NIAID) [E] [b6] Qashu,
Felicia (NIH/OD) [E] [b6] Culp, Michelle (NIH/OD) [E] [b6] Gadbois, Ellen
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadbois]; Wholley, David (FNIH) [T]
[b6] Melencio, Cheryl (FNIH) [T] [b6] Menetski, Joseph (FNIH) [T]
Adam, Stacey (FNIH) [T] [b6] Tountas, Karen (FNIH) [T] [b6]
James, Stephanie (FNIH) [T] [b6] Colvis, Christine (NIH/NCATS) [E] [b6];
Desrosiers, Betsy [b6] Kurilla, Michael (NIH/NCATS) [E] [b6]
Read, Sarah (NIH/NIAID) [E] [b6] Young, John [b6] Paul Gillard
[b6] Hamilton, Holli (OS/ASPR/BARDA) [b6] [b6]
USARMY MEDCOM [b6] (USA) [b6]; Kathleen Neuzil [b6]
Schrage, Stephanie (CDC/DDID/NCIRD/DBD) [zha6@CDC.GOV]; Verani, Jennifer R. (CDC/DDID/NCIRD/DBD)
[b6]; Thornburg, Natalie (CDC/DDID/NCIRD/DVD) [b6] Gonzalez, Nina
[ningonzalez@deloitte.com]; Wachtel, Jonathan [jwachtel@DELOITTE.com]; Stratton, Benjamin
[bstratton@DELOITTE.com]; Anderson, Margaret [marganderson@deloitte.com]; [b6]
dana.carluccio@roseliassociates.com; Bethany Stokes [b6] Arvin, Ann
[b6] Biggerstaff, Matthew (CDC/DDID/NCIRD/ID) [b6]; Cohen, Myron
[b6] Erbelding, Emily (NIH/NIAID) [E] [b6]
[b6] Gruber, Marion (FDA/CBER) [b6]
[b6] Ledgerwood, Julie (NIH/NIAID) [E]
[b6] Marovich, Mary (NIH/NIAID) [E] [b6]
[b6] Laurent Humeau [b6]
[b6] Cheryl Keech [b6] Hughes, Eric [b6]
Denny, Joshua (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=cdb4626dabbb45aa8b8e5d21169344e6-dennyjc]

Subject: ACTIV Vaccines Working Group meeting

Location: Webex: [b6]

Start: 5/28/2020 6:00:00 PM

End: 5/28/2020 7:00:00 PM

Show Time As: Busy

Required Attendees: [b6] Lowy, Douglas (NIH/NCI) [E] [b6] Arvin, Ann; Beth Bell
[b6] Cavaleri Marco; [b6]
[b6] Greg Glenn; [b6]

Optional Attendees: Barton; [b6] Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [b6] USARMY MEDCOM [b6] (USA); Offit, Paul; [b6] Seals, Jonathan (OS/ASPR/BARDA); [b6] Tal Zaks; Tolman, Brett; [b6] Hopps, Markay; Kozlowski, Mary (NIH/NCI) [C]; Johnson, Maureen (NIH/NCI) [E]; [b6] Jeneffer Haynes; [b6]; [b6]; Austin, Sarah (NIH/NIAID) [E]; [b6] Isabel Ramsey; Parker, Ashley (NIH/OD) [E]; Marston, Hilary (NIH/NIAID) [E]; Qashu, Felicia (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James, Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Kurilla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Paul Gillard; Hamilton, Holli (OS/ASPR/BARDA); [b6] USARMY MEDCOM [b6] (USA); Kathleen Neuzil; Schrag, Stephanie (CDC/DDID/NCIRD/DBD); Verani, Jennifer R. (CDC/DDID/NCIRD/DBD); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Gonzalez, Nina; Wachtel, Jonathan; Stratton, Benjamin; Anderson, Margaret; [b6] Bethany Stokes; Ann Arvin; Biggerstaff, Matthew (CDC/DDID/NCIRD/ID); Cohen, Myron; Denny, Joshua (NIH/OD) [E]; [b6] Erbelding, Emily (NIH/NIAID) [E]; [b6]; Gruber, Marion (FDA/CBER); [b6]; Ledgerwood, Julie (NIH/NIAID) [E]; [b6]; Marovich, Mary (NIH/NIAID) [E]; [b6] 'Laurent Humeau'; [b6] Cheryl Keech

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From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
Sent: 5/21/2020 1:29:23 PM
To: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr];

[b6] Lowy, Douglas (NIH/NCI) [E]; [b6]
Arvin, Ann; [b6] Beth Bell; [b6]
[b6] Cavaleri Marco; [b6]
[b6] Greg Glenn; [b6]
[b6] Haynes, Barton; [b6]
Marks, Peter (FDA/CBER); [b6] Mascola, John (NIH/VRC) [E]; [b6]
Messonnier, Nancy (CDC/DDID/NCIRD/OD); [b6] USARMY MEDCOM [b6]
(USA); [b6] Offit, Paul; [b6] Seals, Jonathan
(OS/ASPR/BARDA); [b6]
[b6]
CC: Tolman, Brett [btolman@deloitte.com]; [b6] Hopps, Markay; [b6]
Kozlowski, Mary (NIH/NCI) [C]; [b6] Johnson, Maureen (NIH/NCI) [E]
[b6]; Jeneffer Haynes; [b6]
[b6] Austin, Sarah (NIH/NIAID) [E]
[b6]; Isabel Ramsey; [b6] Parker,
Ashley (NIH/OD) [E]; [b6] Marston, Hilary (NIH/NIAID) [E]; [b6] Qashu,
Felicia (NIH/OD) [E]; [b6] Culp, Michelle (NIH/OD) [E]; [b6] Gadbois, Ellen
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadbois]; Wholley, David (FNIH) [T]
[b6]; Melencio, Cheryl (FNIH) [T]; [b6] Menetski, Joseph (FNIH) [T]
[b6]; Adam, Stacey (FNIH) [T]; [b6] Tountas, Karen (FNIH) [T]; [b6]
James, Stephanie (FNIH) [T]; [b6] Colvis, Christine (NIH/NCATS) [E]; [b6]
Desrosiers, Betsy; [b6]; Hughes, Eric; [b6]; Kurilla, Michael
(NIH/NCATS) [E]; [b6] Read, Sarah (NIH/NIAID) [E]; [b6] Young, John
[b6] Paul Gillard; [b6] Hamilton, Holli (OS/ASPR/BARDA)
[b6] CIV USARMY MEDCOM; [b6] (USA)
[b6]; Kathleen Neuzil; [b6] Schrag, Stephanie
(CDC/DDID/NCIRD/DBD); [b6] Verani, Jennifer R. (CDC/DDID/NCIRD/DBD); [b6]
Thornburg, Natalie (CDC/DDID/NCIRD/DVD); [b6] Gonzalez, Nina [ningonzalez@deloitte.com]; Wachtel,
Jonathan [jwachtel@DELOITTE.com]; Stratton, Benjamin [bstratton@DELOITTE.com]; Anderson, Margaret
[marganderson@deloitte.com]; [b6] Bethany Stokes
[b6]; Arvin, Ann; [b6] Vivek Shinde; [b6]

Subject: ACTIV Vaccines Working Group meeting

Location: Webex; [b6]

Start: 6/4/2020 6:15:00 PM

End: 6/4/2020 7:15:00 PM

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Required Attendees: Santos, Michael (FNIH) [T]; [b6] Lowy, Douglas (NIH/NCI) [E]; [b6]
Arvin, Ann; Beth Bell; [b6] Cavaleri Marco; [b6]
[b6] Greg Glenn; [b6] Haynes,
[b6] Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E];
Messonnier, Nancy (CDC/DDID/NCIRD/OD); [b6] USARMY MEDCOM [b6] (USA); Offit, Paul;
[b6] Seals, Jonathan (OS/ASPR/BARDA); [b6]
[b6] Tal Zaks
Optional Attendees: Tolman, Brett; [b6] Hopps, Markay; Kozlowski, Mary (NIH/NCI) [C]; Johnson, Maureen
(NIH/NCI) [E]; [b6] Jeneffer Haynes; [b6]
[b6] Austin, Sarah (NIH/NIAID) [E]; [b6] Isabel Ramsey; Parker,

Ashley (NIH/OD) [E]; Marston, Hilary (NIH/NIAID) [E]; Qashu, Felicia (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James, Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Kurilla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Paul Gillard; Hamilton, Holli (OS/ASPR/BARDA); [b6] CIV USARMY MEDCOM [b6] (USA); Kathleen Neuzil; Schrag, Stephanie (CDC/DDID/NCIRD/DBD); Verani, Jennifer R. (CDC/DDID/NCIRD/DBD); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Gonzalez, Nina; Wachtel, Jonathan; Stratton, Benjamin; Anderson, Margaret; [b6] Bethany Stokes; Ann Arvin; Vivek Shinde

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From: Menon, Sandeep M [b6]
Sent: 5/21/2020 2:38:51 PM
To: LaVange, Lisa M [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Eron, Joseph J Jr [b6]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price [b6]
[b6] Wohl, David A [b6]; Fischer, William A. II [b6]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; [b6]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Jonathan Li [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]
CC: DeMarcus, Forrest [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jhoanna Roa [b6]; Smith, David [b6]; Paul Klekotka [b6]; Ajay Nirula [b6]; Elsaid, Olivia [oelsaid@deloitte.com]; Robert Jan Benschop [b6]; Lei Shen [b6]
Subject: Re: [EXTERNAL] RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Thanks for the clarification. Then we should be good.

Sandeep

From: "LaVange, Lisa M" [b6]
Date: Thursday, May 21, 2020 at 9:35 AM
To: Sandeep Menon [b6]; "Proschan, Michael (NIH/NIAID) [E]" [b6]; "Eron, Joseph J Jr" [b6]; "Adam, Stacey (FNIH) [T]" [b6]; Judy Currier [b6]; Eric Hughes [b6]; "Read, Sarah (NIH/NIAID) [E]" [b6]; "Rubin, Daniel B. (FDA/CDER)" [b6]; "Farley, John (FDA/CDER)" [b6]; Karen Price [b6]

b6

"Wohl, David A" [b6], "Fischer, William A. II" [b6]
"Javan, Arzhang (NIH/NIAID) [E]" [b6] "Roa, Jhoanna" [b6]
[b6] "Kim, Peter (NIH/NIAID) [E]" [b6], Jonathan Li
[b6] "Marks, Gilbert (OS/ASPR/BARDA) (CTR)" [b6] "Kozak, Marina
(OS/ASPR/BARDA)" [b6]
Cc: "DeMarcus, Forrest" [b6] "Tountas, Karen (FNIH) [T]" [b6]
"Wachtel, Jonathan" <jwachtel@deloitte.com>, Elizabeth Kim <elkim@deloitte.com>, "Parker, Ashley
(NIH/OD) [E]" [b6] Jhoanna Roa [b6], "Smith, David"
[b6] Paul Klekotka [b6] Ajay Nirula [b6]
"Elsaid, Olivia" <oelsaid@deloitte.com>, Robert Jan Benschop [b6], Lei Shen
[b6]

Subject: RE: [EXTERNAL] RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

I think we were thinking about stopping rules based on symptom resolution in the phase 2 portion and clinical endpoints (hosp) in the phase 3 portion. That should be consistent with the decision rule boxes on the slides Karen presented earlier this week.

From: Menon, Sandeep M [b6]
Sent: Thursday, May 21, 2020 9:01 AM
To: Proschan, Michael (NIH/NIAID) [E] [b6] LaVange, Lisa M [b6] Eron,
Joseph J Jr [b6] Adam, Stacey (FNIH) [T] [b6] Judy Currier
[b6]; Eric Hughes [b6] Read, Sarah (NIH/NIAID) [E]
[b6] Price, Dionne (FDA/CDER) [b6] Rubin, Daniel B. (FDA/CDER)
[b6]; Farley, John (FDA/CDER) [b6]; Karen Lynn Price
[b6]
[b6] Wohl, David A [b6] Fischer, William A. II
[b6] Javan, Arzhang (NIH/NIAID) [E] [b6] Roa, Jhoanna [b6]
[b6] Kim, Peter (NIH/NIAID) [E] [b6]; Jonathan Li [b6]
Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6] Kozak, Marina (OS/ASPR/BARDA)
[b6]
Cc: DeMarcus, Forrest [b6]; Tountas, Karen (FNIH) [T] [b6]; Wachtel, Jonathan
<jwachtel@deloitte.com>; Elizabeth Kim <elkim@deloitte.com>; Parker, Ashley (NIH/OD) [E] [b6]
Jhoanna Roa [b6]; Smith, David [b6] Paul Klekotka
[b6] Ajay Nirula [b6] Elsaid, Olivia <oelsaid@deloitte.com>; Robert Jan
Benschop [b6]; Lei Shen [b6]
Subject: Re: [EXTERNAL] RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Agree Mike and Lisa. Not worried about the stats rules, the basic question is what we discussed yesterday. Do we have enough confidence in the assay and the quantitative cut offs and whether it correlates to the clinical endpoint early enough. I am assuming the decision for futility or efficacy stopping will be based on clinical endpoint (and not just the viral load). Based on the discussion yesterday, I heard that we were not sure that viral load correlates with the clinical endpoint.

From: "Proschan, Michael (NIH/NIAID) [E]" [b6]
Date: Thursday, May 21, 2020 at 8:52 AM
To: "LaVange, Lisa M" [b6] "Eron, Joseph J Jr" [b6] "Adam,
Stacey (FNIH) [T]" [b6] Judy Currier [b6], Eric Hughes
[b6] Sandeep Menon [b6], "Read, Sarah (NIH/NIAID)

[E]" [b6] "Rubin, Daniel B.
(FDA/CDER)" [b6] "Farley, John (FDA/CDER)" [b6], Karen Price
[b6]
[b6], "Wohl, David A"
[b6], "Fischer, William A. II" [b6] "Javan, Arzhang
(NIH/NIAID) [E]" [b6] "Roa, Jhoanna" [b6]
[b6], "Kim, Peter (NIH/NIAID) [E]" [b6] Jonathan Li [b6] "Marks,
Gilbert (OS/ASPR/BARDA) (CTR)" [b6] "Kozak, Marina (OS/ASPR/BARDA)"
[b6]
Cc: "DeMarcus, Forrest" [b6] "Tountas, Karen (FNIH) [T]" [b6]
"Wachtel, Jonathan" <jwachtel@deloitte.com>, Elizabeth Kim <elkim@deloitte.com>, "Parker, Ashley
(NIH/OD) [E]" [b6], Jhoanna Roa [b6], "Smith, David"
[b6] Paul Klekotka [b6] Ajay Nirula [b6]
"Elsaid, Olivia" <oelsaid@deloitte.com>, Robert Jan Benschoep [b6], Lei Shen
[b6]

Subject: [EXTERNAL] RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

I think the question is whether we could stop early for efficacy as well as stopping early for futility. That could certainly be incorporated if you think there is a realistic possibility of crossing an efficacy boundary after only 50 people. At the halfway point, the O'Brien-Fleming-like spending function boundary for the z-score is close to 3, so you would have to see a very large z-score to stop that early for efficacy.

Mike.

From: LaVange, Lisa M [b6]
Sent: Thursday, May 21, 2020 7:53 AM
To: Eron, Joseph J Jr [b6]; Adam, Stacey (FNIH) [T] [b6]; Judy Carrier
[b6]; Eric Hughes [b6] Sandeep Menon
[b6]; Proschan, Michael (NIH/NIAID) [E] [b6]; Read, Sarah
(NIH/NIAID) [E] [b6] Price, Dionne (FDA/CDER) [b6] Rubin, Daniel B.
(FDA/CDER) [b6] Farley, John (FDA/CDER) [b6] Karen Lynn Price
[b6]
[b6] Wohl, David A [b6]; Fischer, William A. II
[b6]; Javan, Arzhang (NIH/NIAID) [E] [b6] Roa, Jhoanna [b6]
[b6] Kim, Peter (NIH/NIAID) [E] [b6] Jonathan Li [b6];
Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6] Kozak, Marina (OS/ASPR/BARDA)
[b6]
Cc: DeMarcus, Forrest [b6]; Tountas, Karen (FNIH) [T] [b6]; Wachtel, Jonathan
<jwachtel@deloitte.com>; Elizabeth Kim <elkim@deloitte.com>; Parker, Ashley (NIH/OD) [E] [b6]
Jhoanna Roa [b6]; Smith, David [b6] Paul Klekotka
[b6] Ajay Nirula [b6]; Elsaid, Olivia <oelsaid@deloitte.com>; Robert Jan
Benschoep [b6] Lei Shen [b6]
Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

This seems reasonable to me. We can define any basis that we think will be important for dropping dose arms or entire agents, having little to go on at this point in terms of what best predicts hospitalizations.
Lisa

From: Eron, Joseph J Jr
Sent: Wednesday, May 20, 2020 6:23 PM
To: Adam, Stacey (FNIH) [T] [b6] Judy Carrier [b6]; Eric Hughes

[b6]; LaVange, Lisa M [b6]; Sandeep Menon [b6]; Proschan, Michael (NIH/NIAID) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Price, Dionne (FDA/CDER) [b6]; Rubin, Daniel B. (FDA/CDER) [b6]; Farley, John (FDA/CDER) [b6]; Karen Lynn Price [b6]; Wohl, David A [b6]; Fischer, William A. II [b6]; Javan, Arzhang (NIH/NIAID) [E] [b6]; Roa, Jhoanna [b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Jonathan Li [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]; Kozak, Marina (OS/ASPR/BARDA) [b6];
Cc: DeMarcus, Forrest [b6]; Tountas, Karen (FNIH) [T] [b6]; Wachtel, Jonathan <jwachtel@deloitte.com>; Elizabeth Kim <elkim@deloitte.com>; Parker, Ashley (NIH/OD) [E] < [b6] Jhoanna Roa [b6]; Smith, David [b6]; Paul Klekotka [b6]; Ajay Nirula [b6]; Elsaid, Olivia <oelsaid@deloitte.com>; Robert Jan Benschop [b6]; Lei Shen [b6];
Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Here is my question for the group – especially Michael, John and Lisa

My question is whether there could be an interim “activity” analysis similar to the futility analysis listed below – the reason I ask is we have very little longitudinal data on the quantitative viral shedding and it is possible that this endpoint would have substantial power such that 50 patients per arm could provide an antiviral answer.

- If the Phase 2 portion of the Clinical mAb protocol is used for dose finding, this may be challenging with respect to size of the trial (number of treatment arms needed and available sample size per treatment arm). In addition, it may be appropriate to establish an interim futility analysis based on change in quantitative viral shedding to allow for discontinuation of a dose after e.g. 50 rather than 110 patients, or to allow early discontinuation of high doses due to safety findings.

Joe Eron MD
Professor of Medicine
University of North Carolina at Chapel Hill
School of Medicine

[b6]

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Wednesday, May 20, 2020 5:42 PM
To: Judy Carrier [b6]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Sandeep Menon [b6]; Proschan, Michael (NIH/NIAID) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Price, Dionne (FDA/CDER) [b6]; Rubin, Daniel B. (FDA/CDER) [b6]; Farley, John (FDA/CDER) [b6]; Karen Lynn Price [b6]; Wohl, David A [b6]; Fischer, William A. II [b6]; Eron, Joseph J Jr [b6]; Javan, Arzhang (NIH/NIAID) [E] [b6]; Roa, Jhoanna [b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Jonathan Li [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]; Kozak, Marina (OS/ASPR/BARDA) [b6];
Cc: DeMarcus, Forrest [b6]; Tountas, Karen (FNIH) [T] [b6]; Wachtel, Jonathan <jwachtel@deloitte.com>; Elizabeth Kim <elkim@deloitte.com>; Parker, Ashley (NIH/OD) [E] < [b6] Jhoanna Roa [b6]; Eron, Joseph J Jr [b6]; Smith, David [b6]; Paul Klekotka [b6]; Ajay Nirula [b6]; Elsaid,

Olivia <oelsaid@deloitte.com>; Robert Jan Benschop [b6]; Lei Shen [b6]

Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Dear mAb Outpatient WT,

The FDA team that has been working with ACTIV and sitting in on our writing team meetings for this protocol would like to offer the attached thoughts for the group's consideration on tonight's call.

Also, attaching again the updated synopsis that was discussed with the mAb Steering Committee earlier today.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] | Mobile: [b6]

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Sent: 5/21/2020 3:26:14 PM
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[b6]; Cohen, Myron [b6]; Corey, Larry [b6]
Desrosiers, Betsy [b6]; Dickens, Jim (NIH/NCATS) [C] [b6]
Doroshov, James (NIH/NCI) [E] [b6]; Goff, David (NIH/NHLBI) [E] [b6]; Kurilla, Michael (NIH/NCATS) [E] [b6]; Nayak, Seema (NIH/NIAID) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Payton, Manizhe (NIH/NIAID) [E] [b6]; Resnansky, Laura [b6]
Srinivasan, Badhri [b6]; Stern, Peter (FDA/CDER) [b6]
Wachtel, Jonathan [jwachtel@deloitte.com]; Qashu, Felicia (NIH/OD) [E] [b6]
Vincent, Mike [b6]
CC: Colvis, Christine (NIH/NCATS) [E] [b6]; Jansen, Kathrin [b6]; Lowy, Douglas (NCI) [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Young, John [b6]
Adam, Stacey (FNIH) [T] [b6]; Anderson, Margaret [marganderson@deloitte.com]; Carluccio, Dana [b6]; Melencio, Cheryl (FNIH) [T] [b6]
Collins, Francis (NIH/OD) [E] [b6]; Gonzalez, Nina [ningonzalez@deloitte.com]; Heaton, Penny [b6]; James, Stephanie (FNIH) [T] [b6]
Li, Rose [b6]; Menetski, Joseph (FNIH) [T] [b6]
Santos, Michael (FNIH) [T] [b6]; Tuveson, Nancy [b6]; Wholley, David (FNIH) [T] [b6]
Criffield, Robin [b6]; Minnich, Beth [b6]
Katz, Rebecca (NIH/NCATS) [E] [b6]; Stratton, Benjamin [bstratton@DELOITTE.com]; Tolman, Brett [btolman@deloitte.com]; Victoria Davey [b6]
Jintanat Ananworanich [b6]; Sizemore, Christine (NIH/FIC) [E] [b6]
Kenny, Dermot [b6]; Weinmann, Gail (NIH/NHLBI) [E] [b6]
Mensah, George (NIH/NHLBI) [E] [b6]; Garner, Carlos [b6]; Denny, Joshua (NIH/OD) [E] [b6]
Reid, Nancy (NIH/OD) [C] [b6]; Gebo, Kelly (NIH/OD) [b6]
Moschetti, Justin (NIH/OD) [E] [b6]; Culp, Michelle (NIH/OD) [E] [b6]
Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Hughes, Eric [b6]
Hamilton, Nancy [b6]

Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting
Attachments: Clinical Trial Capacity Working Group Meeting Agenda_05222020.pdf; ACTIV Protocol Tracker 05212020.pdf
Location: [b6]

Start: 5/22/2020 1:00:00 PM
End: 5/22/2020 2:00:00 PM
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Recurrence: Weekly
every Tuesday and Friday from 9:00 AM to 10:00 AM

Required Attendees: Vincent, Mike; Bascles, Lionel; Cohen, Myron; Corey, Larry; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshov, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; Kurilla, Mike; Nayak, Seema (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Payton, Manizhe; Resnansky, Laura; Srinivasan, Badhri; Stein, Peter (FDA/CDER); Wachtel, Jonathan; Qashu, Felicia

Optional Attendees: Sizemore, Christine (NIH/FIC) [E]; Kenny, Dermot; Weinmann, Gail (NIH/NHLBI) [E]; Mensah, George (NIH/NHLBI) [E]; Garner, Carlos; Denny, Joshua (NIH/OD) [E]; Reid, Nancy (NIH/OD) [C]; Gebo, Kelly (NIH/OD) [G]; Moschetti, Justin (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Carluccio, Dana; Cheryl (FNIH) Melencio [T] [b6]; Francis Collins; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH); Tuveson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Minnich, Beth; Rebecca (NIH/NCATS) Katz [E] [b6]
Stratton, Benjamin; Tolman, Brett; Davey, Victoria; Jintanat Ananworanich

Dear Colleagues, Attached is the Agenda. Please note that we will be hearing from the All of Us program and how they might be useful for implementing ACTIV protocols. In addition, per a request from Tuesday's meeting, attached is the ACTIV Protocol Quick Reference Tracker – thanks to Jonathan and his colleagues for creating this! At present there are three ACTIV protocols, all in the treatment category. CTC Recommendations Committees have been established for the ACTIV-1 and ACTIV-2 protocols to-date and integration with the protocol development and lead network operations teams will take place in the very near future. Best regards, Karen

ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines

Dear Clinical Trial Capacity Working Group members,

In anticipation of this working group making rapid progress on identified action items and other activities, the co-chairs have agreed that it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify areas of need, and to determine next steps. We ask that you make every effort possible to join each of these meetings, but understand that at times you may have competing priorities. To place a hold on your calendar, please accept this meeting invite with a response; later you can decline an individual meeting if you have a conflict.

An agenda and other meeting materials, as needed, will be distributed prior to each call.

With best regards,
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health

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CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Jintanat Ananworanich [b6]; Walker, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e577497e37b244168bd76c0b8827ca71-Robert.Walk]; Mason, Robin (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77156b112de94c439dbccb6894954618-Robin.Mason]; Hughes, Eric [b6]; Criffield, Robin [b6]; Hamilton, Nancy [b6]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Minnich, Beth [b6]; Mueller-Reichenstein, Petra [b6]; Quadros, Nora [b6]; Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Hill, Zoe (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [marganderson@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Carluccio, Dana [b6]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny [b6]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [b6]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH)

[T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveson, Nancy [b6] Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Jansen, Kathrin [b6] Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [b6]

Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting
Attachments: Clinical Trial Capacity Working Group Meeting Agenda_05262020.pdf
Location: [b6]

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Optional Attendees: Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Jintanat Ananworanich; Walker, Robert (OS/ASPR/BARDA); Mason, Robin (OS/ASPR/BARDA); Hughes, Eric; Criffield, Robin; Hamilton, Nancy; Melencio, Cheryl (FNIH) [T]; Minnich, Beth; Mueller-Reichenstein, Petra; Quadros, Nora; Rebecca (NIH/NCATS) Katz [E] [b6] Zoe (NIH/NHLBI) Hill [C] [b6] Adam, Stacey (FNIH) [T]; Anderson, Margaret; Ashley (NIH/OD) Parker [E] [b6] Carluccio, Dana; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH); Tuveson, Nancy; Wholley, David (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John

Dear Colleagues, Attached is the Agenda for the Clinical Trial Capacity Working Group agenda. I am please to let you know that BARDA (Biomedical Advanced Research and Development Authority, U.S. Dept of Health and Human Services) will join the meeting to talk about their CRO relationships. With best regards, Karen

Dear Clinical Trial Capacity WG members, This will extend our full working group calls through the end of May. We'll assess the need for further meetings at the end of the month. Many thanks for your participation! Karen

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[b6] Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [b6] Jansen, Kathrin [b6] Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [b6]

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every Tuesday and Friday from 9:00 AM to 10:00 AM
Required Attendees: Garner, Carlos; Bascles, Lionel; Vincent, Mike; Payton, Manzone; Cohen, Myron; Corey, Larry; Davey, Victoria; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshov, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; Kurilla, Mike; Nayak, Seema (NIH/NIAID) [E]; Qashu, Felicia; Resnansky, Laura; Sizemore, Christine (NIH/FIC) [E]; Srinivasan, Badhri; Stein, Peter (FDA/CDER); Wachtel, Jonathan; Mensah, George; Weinmann, Gail
Optional Attendees: Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Kublin MD, MPH, James; Ferguson, Sue; Kenny, Dermot; Gonzalez, Nina; Criffield, Robin; Hamilton, Nancy; Melencio, Cheryl (FNIH) [T]; Minnich, Beth; Mueller-Reichenstein, Petra; Quadros, Nora; Rebecca (NIH/NCATS) Katz [E] [b6] Zoe (NIH/NHLBI) Hill [C] [b6] Adam, Stacey (FNIH) [T]; Anderson, Margaret; Ashley (NIH/OD) Parker [E] [b6] Carluccio, Dana; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Mariael (FNIH); Tuvesson, Nancy; Wholley, David (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John

Colleagues – Attaching the agenda for the call. Best, Karen

Dear Clinical Trial Capacity WG members, This will extend our full working group calls through the end of May. We'll assess the need for further meetings at the end of the month. Many thanks for your participation! Karen

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Meeting ID: [b6]
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US (New York)
US (Germantown)
US (Tacoma)
US (Houston)
US (San Jose)
US (San Jose)

Meeting ID: [b6]

Password: **b6**
Find your local number: **b6**

From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 5/21/2020 3:33:55 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp];

b6
b6 Baric, Ralph
b6
b6 Deming, Damon (FDA/CDER) b6
b6 Parker, Ashley (NIH/OD) [E] b6 Collins, Francis
(NIH/OD) [E] b6 Adams, Peter (OS/ASPR/BARDA)
b6 Rao, Srinivas /US b6 Anderson, James (NIH/OD) [E]
b6 Tomas Cihlar b6 Qashu, Felicia (NIH/OD) [E]
b6
CC: Nancy Haigwood b6 Diamond, Michael b6 Wholley, David (FNIH) [T]
b6 Austin, Christopher (NIH/NCATS) [E] b6 Melencio, Cheryl (FNIH) [T]
Colvis, Christine (NIH/NCATS) [E] b6 Desrosiers, Betsy
b6 Hughes, Eric b6 Jansen, Kathrin
b6 Kurilla, Michael (NIH/NCATS) [E] b6 Lowy, Douglas (NCI)
b6 Read, Sarah (NIH/NIAID) [E] b6 Tountas, Karen (FNIH) [T]
b6 Santos, Michael (FNIH) [T] b6 Adam, Stacey (FNIH) [T] b6
James, Stephanie (FNIH) [T] b6 Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Kim, Elizabeth
[elkim@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Wachtel, Jonathan [jwachtel@deloitte.com];
Prabhavathi Fernandes b6 Rose Li b6 Dana Carluccio
b6 Lagos, Enrique (NIH/NCATS) [E] b6 Jonson, Samantha
(NIH/NCATS) [E] b6 Gonzalez, Nina [ningonzalez@deloitte.com]; Simon, Dina (NIH/OD) [C]
b6 Burrus-Shaw, Cyndi (NIH/OD) [E] b6 Rodriguez, Robin D
b6 Dave Frankowski b6 Lowy, Douglas (NIH/NCI) [E]
b6 Florence, Clint (NIH/NIAID) [E] b6 b6
b6 USARMY b6
Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Hild, Sheri (NIH/OD) [E]
b6

Subject: ACTIV Preclinical working group (Friday meeting)

Location: b6

Start: 5/22/2020 3:00:00 PM

End: 5/22/2020 4:00:00 PM

Show Time As: Busy

Recurrence: Weekly
every Friday from 11:00 AM to 12:00 PM

Required Attendees:

b6

Optional Attendees:

b6 Parker,
Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; b6 Adams, Peter
(OS/ASPR/BARDA); Rao, Srinivas /US; Anderson, James (NIH/OD) [E]; Tomas Cihlar; Qashu, Felicia (NIH/OD) [E]
Diamond, Michael; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T];
Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E];
Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam,
Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel,
Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha
(NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D;
Dave Frankowski; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Louise Pitt b6

Holding time

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US
US (Houston)
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Password: **b6**

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From: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
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[b6]
[b6] Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
[b6] Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
[b6] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras];
[b6] Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [b6] Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [b6] USARMY MEDCOM [b6] (USA) [b6]
Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; [b6]
[b6]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [b6] Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [kathrin.jansen@pfizer.com]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Kim, Elizabeth [elkim@deloitte.com]; Tolman, Brett [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan [jwachtel@deloitte.com]; Prabhavathi Fernandes [b6] Diamond, Michael [b6] Rose Li

[b6] Dana Carluccio [b6] Lagos, Enrique (NIH/NCATS)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha
(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D
[b6] Dave Frankowski [b6] antoinette_baric
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userb6b844cf]; Lowy,
Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood
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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188];
Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8];
Mason, Stephen [b6]; Connelly, Sarah
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab];
[b6] Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; K C Kent Lloyd
[b6] Embry, Alan (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=882a18a10a134c49acac21cb83fd599d-embrya];
Lerner, Andrea (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=53254f4fb04e4bcbabe37940b4b41887-fennellyam]

Subject: ACTIV Preclinical full working group

Attachments: Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; ACTIV Preclinical full working group; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Subgroup discussion of prediction of therapy resistance from emerging viral sequence data; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Canceled: ACTIV Preclinical full working group; Untitled Attachment; Untitled Attachment; Untitled Attachment

Location: [b6]

Start: 1/13/2021 3:00:00 PM

End: 1/13/2021 4:00:00 PM

Show Time As: Tentative

Recurrence: Monthly
the second Wednesday of every 1 month(s) from 10:00 AM to 11:00 AM

Required Attendees: Hild, Sheri (NIH/OD) [E]; [b6]

[b6]
[b6] Parker,
Ashley (NIH/OD) [E]; [b6] Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu,
Felicia (NIH/OD) [E]; Tomas Cihlar [b6] USARMY MEDCOM [b6] (USA); Punturieri, Antonello

(NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; b6

b6

**Optional
Attendees:**

Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; b6 Connelly, Sarah; b6 Lumsden, Joanne (NIH/NCATS) [C]; K C Kent Lloyd; b6 Embry, Alan (NIH/NIAID) [E]; Lerner, Andrea (NIH/NIAID) [E]

Changing time for preclinical WG

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US (San Jose)
US (Tacoma)
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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/21/2020 4:14:59 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [b6]; Eisner, Mark [b6]; Gottesdiener, Keith [b6]; Hughes, Eric [b6]; Judy Carrier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [elkim@deloitte.com]; LaVange, Lisa [b6]; Levy, Elliot [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Patel, Naimish [b6]; Peppercorn, Amanda [b6]; Poole, Mike [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coll]; Amanda Peppercorn [b6]; Garner, Carl [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Burgess, Timothy [b6]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel];
CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [b6]; Jansen, Kathrin [b6]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John
[b6]; Biggs, Mary [b6]; Butcher, Tina [b6];
Demarcus [b6]; Macone, Erin [b6]; Melencio, Cheryl (FNIH) [T]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla
[b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH)
[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan
[jwachtel@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Alvarez, Rosa [rosalvarez@deloitte.com];
Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [b6]; Rose
Li Central Account [FNIH@roseliassociates.com]; Anderson, Margaret [marganderson@deloitte.com]; Lucas
Smalldon [b6]; Stratton, Benjamin [bstratton@DELOITTE.com];
[b6] Mollica, Linda /US [b6] Qashu, Felicia (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy
(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Goff, David (NIH/NHLBI) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Rubin, Daniel B. (FDA/CDER)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]

Subject: ACTIV TX-Clinical Working Group Meeting #7
Attachments: ACTIV Therapeutics-Clinical Full Working Group_21May2020 Meeting Guide.pdf
Location: [b6]

Start: 5/21/2020 6:00:00 PM
End: 5/21/2020 7:00:00 PM
Show Time As: Busy

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]

Optional Attendees: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; [b6]; Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; [b6]; Rubin, Daniel B. (FDA/CDER)

Dear ACTIV TX-Clinical WG,

Looking forward to seeing you all soon at the meeting. Please find attached the slides for the meeting.

Thanks,
Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/21/2020 4:19:16 PM
To: Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetz]; Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [b6]; Keith Gottesdiener [b6]; Elliott Levy [b6]; Wung, Peter /US [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [b6]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bafd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Rose Li Central Account [FNIH@roseliassociates.com]
Subject: RE: ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #12

Thanks, Walter!

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [b6] | Mobile: [b6]

From: Koroshetz, Walter (NIH/NINDS) [E] [b6]
Sent: Thursday, May 21, 2020 11:30 AM
To: Adam, Stacey (FNIH) [T] [b6]; Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Ruxandra Draghia-Akli [b6]; Mellors, John W [b6]; Naimish Patel [b6]; Colvis, Christine (NIH/NCATS) [E] [b6]; Young, John [b6]; Stein, Peter (FDA/CDER) [b6]; Poole, Mike [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [b6]; Vincent, Michael [b6]; Keith Gottesdiener [b6]; Elliott Levy [b6]; Wung, Peter /US [b6]; Higgs, Elizabeth (NIH/NIAID) [E]

b6

Carlos O Garner

b6

Goff, David (NIH/NHLBI) [E]

Cc: Elizabeth Kim <elkim@deloitte.com>; Menetski, Joseph (FNIH) [T]; b6 Alvarez, Rosa Maria <rosalvarez@deloitte.com>; Salathin, Carla b6 Parker, Ashley (NIH/OD) [E] b6; Wholley, David (FNIH) [T] b6; Melencio, Cheryl (FNIH) [T] b6 Lucas Smalldon b6 Walker, Paula (NIH/NINDS) [E] b6 Ward, Jackie (NIH/NINDS) [E] b6, Rose Li Central Account <FNIH@roseliassociates.com>

Subject: RE: ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #12

Links to the most relevant part of the CTSAs—Some of the Trial Innovation are powerhouses for clinical trials (Duke/Vanderbilt? . TICs

Center for Innovative Trials in Children and Adults (TRIDENT)(link is external)

Institutions: Duke University and Vanderbilt University Medical Center

Principal Investigators: Daniel K. Benjamin, Jr., M.D., Ph.D. (Duke), and Gordon R. Bernard, M.D. (Vanderbilt)

Utah Trial Innovation Center(link is external)

Institution: University of Utah

Principal Investigator: Jonathan Michael Dean, M.D.

Johns Hopkins-Tufts Trial Innovation Center(link is external)

Institutions: Johns Hopkins University and Tufts University

Principal Investigators: Daniel F. Hanley, M.D. (Johns Hopkins), Daniel E. Ford, M.D. (Johns Hopkins), and Harry P. Selker, M.D. (Tufts University)

Walter

-----Original Appointment-----

From: Adam, Stacey (FNIH) [T] b6

Sent: Wednesday, May 20, 2020 9:50 PM

To: Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; Mellors, John W; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E]

Cc: Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; b6 Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/NINDS) [E]; Rose Li Central Account

Subject: ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #12

When: Thursday, May 21, 2020 11:00 AM-12:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: b6

Dear TX-Clinical Agent Prioritization Subgroup,

Please find attached the formal summary from yesterday's meeting.

In addition, please find the slides for tomorrow's meetings. Please let me know if you have any amendments or additions.

Thanks,
Stacey

APAR0000005316

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/21/2020 4:44:16 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [b6]; Eisner, Mark [b6]; Gottesdiener, Keith [b6]; Hughes, Eric [b6]; Judy Carrier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [elkim@deloitte.com]; LaVange, Lisa [b6]; Levy, Elliot [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [b6]; Peppercorn, Amanda [b6]; Poole, Mike [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coll]; Amanda Peppercorn [b6]; Garner, Carl [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96c8ff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Burgess, Timothy [b6]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-roosenbey]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [b6]; Jansen, Kathrin [b6]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [b6]; Biggs, Mary [b6]; Butcher, Tina [b6]

Demarcus [b6] Macone, Erin [b6]; Melencio, Cheryl (FNIH) [T]
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 [b6] Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan
 [jwachtel@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Alvarez, Rosa [rosalvarez@deloitte.com];
 Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [b6] Rose
 Li Central Account [FNIH@roseliassociates.com]; Anderson, Margaret [marganderson@deloitte.com]; Lucas
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 [b6] Mollica, Linda /US [b6]; Qashu, Felicia (NIH/OD) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Rubin, Daniel B. (FDA/CDER)
 [/o=ExchangeLabs/ou=Exchange Administrative Group
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Subject: ACTIV TX-Clinical Working Group Meeting #7
Attachments: ACTIV Therapeutics-Clinical Full Working Group_21May2020 Meeting Guide.pdf
Location: [b6]

Start: 5/21/2020 6:00:00 PM
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Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]

Optional Attendees: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; [b6] Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] [b6] Rubin, Daniel B. (FDA/CDER)

Dear ACTIV TX-Clinical WG,

Looking forward to seeing you all soon at the meeting. Please find attached the slides for the meeting.

Thanks,
Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/21/2020 4:44:18 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [b6]; Eisner, Mark [b6]; Gottesdiener, Keith [b6]; Hughes, Eric [b6]; Judy Carrier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [elkim@deloitte.com]; LaVange, Lisa [b6]; Levy, Elliot [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [b6]; Peppercorn, Amanda [b6]; Poole, Mike [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coll]; Amanda Peppercorn [b6]; Garner, Carl [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Burgess, Timothy [b6]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [b6]; Jansen, Kathrin [b6]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [b6]; Biggs, Mary [b6]; Butcher, Tina [b6]

Demarcus [b6] Macone, Erin [b6] Melencio, Cheryl (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla
 [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T]
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 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan
 [jwachtel@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Alvarez, Rosa [rosalvarez@deloitte.com];
 Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [b6] Rose
 Li Central Account [FNIH@roseliassociates.com]; Anderson, Margaret [marganderson@deloitte.com]; Lucas
 Smalldon [b6]; Stratton, Benjamin [bstratton@DELOITTE.com];
 [b6]; Mollica, Linda /US [Linda.Mollica@sanofi.com]; Qashu, Felicia (NIH/OD) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Goff, David (NIH/NHLBI) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Rubin, Daniel B. (FDA/CDER)
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]

Subject: Slides for ACTIV TX-Clinical Working Group Meeting #7

Attachments: ACTIV Therapeutics-Clinical Full Working Group_21May2020 Meeting Guide.pdf

Dear ACTIV TX-Clinical WG,

Looking forward to seeing you all soon at the meeting. Please find attached the slides for the meeting.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [b6] Mobile: [b6]

Join Zoom Meeting

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Meeting ID: [b6]

Password: [b6]

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US (Houston)

b6

US (San Jose)

US (San Jose)

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b6

Find your local number:

b6

From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 5/21/2020 4:54:26 PM
To: Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; [b6] Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; [b6] [b6] (USA) [b6] [b6]
[b6] Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; [b6] Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcdb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; [b6] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Rao, Srinivas [b6] Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [b6]
CC: Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [b6] Hughes, Eric [b6] Jansen, Kathrin [b6] Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Kim, Elizabeth [elkim@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Wachtel, Jonathan [jwachtel@deloitte.com]; Prabhavathi Fernandes [b6] Diamond, Michael [b6] Rose Li [b6] Dana Carluccio [b6] Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagosel]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [b6]; Dave Frankowski [b6]; Baric, Toni C [b6]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin [bstratton@DELOITTE.com]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]

Subject: RE: ACTIV Preclinical working group (Tuesday meeting)

Attachments: 2020-05-20_Preclinical_WG_Summary_F1.docx

Dear Preclinical Working group members and attendees,

Please find the minutes from yesterday's meeting attached. Thank you for a very interesting meeting and all of the work you continue to do for the ACTIV effort.

Best regards,
Joe and Rosa

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T]

Sent: Tuesday, April 14, 2020 6:43 PM

To: [b6]
Adams, Peter (OS/ASPR/BARDA); [b6] (USA); Menetski, Joseph (FNIH) [T];

b6

Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar
Cc: Simon, Dina (NIH/OD) [C]; Florence, Clint (NIH/NIAID) [E]; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]

Subject: ACTIV Preclinical working group (Tuesday meeting)

When: Wednesday, May 20, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: [b6]

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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Password: [b6]

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	US (Chicago)
	US (New York)
	US (San Jose)
	US (San Jose)
	US (Tacoma)
	US (Houston)

Meeting ID:	b6
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Password:	b6
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Find your local number:	b6
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From: Michael Hughes [b6]
Sent: 5/21/2020 5:48:46 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; LaVange, Lisa M [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Eron, Joseph J Jr [b6]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [b6]; Sandeep Menon [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price [b6]; smith.davey [b6]; Wohl, David A [b6]; Fischer, William A. II [b6]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; [b6] Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; li.jonathan [b6] Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]
CC: DeMarcus, Forrest [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; roa.jhoanna [b6]; Smith, David [b6]; Paul Klekotka [b6]; Ajay Nirula [b6]; Elsaid, Olivia [oelsaid@deloitte.com]; Robert Jan Benschop [b6]; Lei Shen [b6]
Subject: Re: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Hi Stacey:

Tomorrow, I can make the following times:

8-9:30 EDT

10:30-2 EDT

4:30 onwards EDT

Michael

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Thursday, May 21, 2020 1:41 PM
To: LaVange, Lisa M; Michael Hughes; Proschan, Michael (NIH/NIAID) [E]; Eron, Joseph J Jr; currier.judith; Eric Hughes;

APAR0000005313

Sandeep Menon; read.sarah; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; [b6] chew.kara; Wohl, David A; Fischer, William A. II; javan.arzhang; Roa, Jhoanna; [b6] kim.peter; li.jonathan; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Kozak, Marina (OS/ASPR/BARDA)

Cc: DeMarcus, Forrest; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; roa.jhoanna; Smith, David; Paul Klekotka; Ajay Nirula; Elsaid, Olivia; Robert Jan Benschop; Lei Shen

Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Hi Lisa,

You are correct. I did have on my to do list for today to get together a meeting of the statistical team for either tonight, tomorrow, or Saturday, according to my notes.

I was going to send a note to the stats group for their availability, but if you all wanted to suggest times for tomorrow that you are available on this thread, I will work to get a meeting scheduled and an invite out.

Thanks,
STacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: [b6] Mobile: [b6]

From: LaVange, Lisa M [b6]

Sent: Thursday, May 21, 2020 1:34 PM

Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Thanks, Michael. I believe it is premature to submit the protocol to your internal review committee. My take-away from yesterday's meeting was that the next step would be for the subgroup of statisticians to meet to discuss the simulations required for the revised trial design. The proposed revisions to the design are needed, in my opinion, to give us the type of flexible, fast-moving master protocol we need to screen a large amount of monoclonal antibodies. But we need to work out some of the design details, so let's have that next meeting as planned. Hoping we can schedule it for some time tomorrow and will work with Stacey to find a time.

Lisa

From: Michael Hughes [b6]

Sent: Thursday, May 21, 2020 11:03 AM

Subject: Re: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Hi All:

The ACTG team was hoping [b5] tomorrow to the NIAID Clinical Science Review Committee for their review. The protocol design uses standard (widely-used) statistical methods for interim and final analyses but we received the feedback (attached) from ACTIV [b5] [b5], so wanted to respond and get thoughts back as this is a substantial change --- and would mean that we would not be able to send for CSRC tomorrow.

I have particular concerns about the need to use the Bayesian paradigm, particularly for Phase III. For a given agent, the Phase 3 study is a fairly simple study involving evaluations for safety, clinical symptoms, and the primary outcome measure of hospitalization/death. We proposed to use standard group sequential monitoring methods which are flexible (using the Lan-DeMets approach for flexible timing of interim analyses with an O'Brien and Fleming type stopping guideline). I think the seamless phase II to phase 3 aspect of the design can be incorporated into this flexible approach by just considering the "look" at the data at the end of phase II as one "look" at the phase 3 primary outcome. This provides protection for the Type I error rate for each specific agent. We can overlay a the possibility of a simple futility rule, eg at $\geq 50\%$ enrollment, to allow stopping for lack of effect (can be justified using a Type II spending boundary, conditional power, or even a Bayesian type rule).

I think this is all quite straightforward. I worry that putting the Phase 3 trial into the Bayesian paradigm gains very little but adds complexity in terms of having to confirm that any Bayesian decision rule does protect Type I error rate for regulatory purposes, and in terms of explaining to many different companies and ultimately to a broad audience. In addition, if the study does go global, it increases the complexity of explaining to IRBs and other review groups.

I would prefer to leave Phase 3 using standard (widely used) statistical methods. I would also favor using standard methods for analysis of Phase 2 data but do agree that Bayesian analyses might also be used for the main efficacy outcome measures to provide an additional perspective in decision-making --- though the main graduation rules (eg observing an absolute 20% reduction in % positive for SARS-CoV-2 at an measurement time, and/or a 20% reduction in mean symptom duration) are straightforward and well-powered.

I would welcome feedback.

Many thanks,
Michael

From: Proschan, Michael (NIH/NIAID) [E]

b6

Sent: Thursday, May 21, 2020 8:52 AM

To: LaVange, Lisa M; Eron, Joseph J Jr; Adam, Stacey (FNIH) [T]; currier.judith; Eric Hughes; Sandeep Menon; read.sarah; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; smith.davey; Michael Hughes;

b6

chew.kara; Wohl, David A; Fischer, William A. II; javan.arzhang; Roa, Jhoanna;

b6

kim.peter; li.jonathan; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Kozak, Marina (OS/ASPR/BARDA)
Cc: DeMarcus, Forrest; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; roa.jhoanna; Smith, David; Paul Klekotka; Ajay Nirula; Elsaid, Olivia; Robert Jan Benschop; Lei Shen

Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

I think the question is:

b5

b5

Mike.

From: LaVange, Lisa M [b6]
Sent: Thursday, May 21, 2020 7:53 AM
To: Eron, Joseph J Jr [b6]; Adam, Stacey (FNIH) [T] [b6]; Judy Carrier [b6]; Eric Hughes [b6]; Sandeep Menon [b6]; Proschan, Michael (NIH/NIAID) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Price, Dionne (FDA/CDER) [b6]; Rubin, Daniel B. (FDA/CDER) [b6]; Farley, John (FDA/CDER) [b6]; Karen Lynn Price [b6]; Wohl, David A [b6]; Fischer, William A. II [b6]; Javan, Arzhang (NIH/NIAID) [E] [b6]; Roa, Jhoanna [b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Jonathan Li [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]; Kozak, Marina (OS/ASPR/BARDA) [b6];
Cc: DeMarcus, Forrest [b6]; Tountas, Karen (FNIH) [T] [b6]; Wachtel, Jonathan <jwachtel@deloitte.com>; Elizabeth Kim <elkim@deloitte.com>; Parker, Ashley (NIH/OD) [E] [b6]; Jhoanna Roa [b6]; Smith, David [b6]; Paul Klekotka [b6]; Ajay Nirula [b6]; Elsaid, Olivia <oelsaid@deloitte.com>; Robert Jan Benschop [b6]; Lei Shen [b6]
Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

This seems reasonable to me. [b5]
[b5]
Lisa

From: Eron, Joseph J Jr
Sent: Wednesday, May 20, 2020 6:23 PM
To: Adam, Stacey (FNIH) [T] [b6]; Judy Carrier [b6]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Sandeep Menon [b6]; Proschan, Michael (NIH/NIAID) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Price, Dionne (FDA/CDER) [b6]; Rubin, Daniel B. (FDA/CDER) [b6]; Farley, John (FDA/CDER) [b6]; Karen Lynn Price [b6]; Wohl, David A [b6]; Fischer, William A. II [b6]; Javan, Arzhang (NIH/NIAID) [E] [b6]; Roa, Jhoanna [b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Jonathan Li [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]; Kozak, Marina (OS/ASPR/BARDA) [b6];
Cc: DeMarcus, Forrest [b6]; Tountas, Karen (FNIH) [T] [b6]; Wachtel, Jonathan <jwachtel@deloitte.com>; Elizabeth Kim <elkim@deloitte.com>; Parker, Ashley (NIH/OD) [E] [b6]; Jhoanna Roa [b6]; Smith, David [b6]; Paul Klekotka [b6]; Ajay Nirula [b6]; Elsaid, Olivia <oelsaid@deloitte.com>; Robert Jan Benschop [b6]; Lei Shen [b6]
Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Here is my question for the group – especially Michael, John and Lisa
My question [b5]

[b5]

[b5]

b5

Joe Eron MD
Professor of Medicine
University of North Carolina at Chapel Hill
School of Medicine

b6

From: Adam, Stacey (FNIH) [T] **b6**
Sent: Wednesday, May 20, 2020 5:42 PM
To: Judy Currier **b6**; Eric Hughes **b6** LaVange, Lisa M
b6 Sandeep Menon **b6** Proschan, Michael (NIH/NIAID) [E]
b6; Read, Sarah (NIH/NIAID) [E] **b6** Price, Dionne (FDA/CDER)
b6 Rubin, Daniel B. (FDA/CDER) **b6** Farley, John (FDA/CDER)
b6; Karen Lynn Price **b6**
b6 Wohl, David A
b6 Fischer, William A. II **b6**; Eron, Joseph J Jr
b6 Javan, Arzhang (NIH/NIAID) [E] **b6**; Roa, Jhoanna **b6**
b6 Kim, Peter (NIH/NIAID) [E] **b6** Jonathan Li **b6**;
Marks, Gilbert (OS/ASPR/BARDA) (CTR) **b6** Kozak, Marina (OS/ASPR/BARDA)
b6
Cc: DeMarcus, Forrest **b6** Tountas, Karen (FNIH) [T] **b6**; Wachtel, Jonathan
<jwachtel@deloitte.com>; Elizabeth Kim <elkim@deloitte.com>; Parker, Ashley (NIH/OD) [E] **b6**
Jhoanna Roa **b6**; Eron, Joseph J Jr **b6**; Smith, David
b6; Paul Klekotka **b6**; Ajay Nirula **b6** Elsaid,
Olivia <oelsaid@deloitte.com>; Robert Jan Benschop **b6** Lei Shen **b6**
Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Dear mAb Outpatient WT,

The FDA team that has been working with ACTIV and sitting in on our writing team meetings for this protocol would like to offer the attached thoughts for the group's consideration on tonight's call.

Also, attaching again the updated synopsis that was discussed with the mAb Steering Committee earlier today.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: **b6** | Mobile: **b6**

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Password: **b6**

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US (Houston)
US (San Jose)
US (San Jose)

Meeting ID:

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Password:

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Find your local number:

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From: Michael Hughes [b6]
Sent: 5/21/2020 5:54:02 PM
To: LaVange, Lisa M [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Eron, Joseph J Jr [b6]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jcurrier.m]; Eric Hughes [b6]; Sandeep Menon [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price [b6]; smith.davey [b6]; [b6]; Wohl, David A [b6]; Fischer, William A. II [b6]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; [b6] Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; li.jonathan [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]
CC: DeMarcus, Forrest [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; roa.jhoanna [b6]; Smith, David [b6]; Paul Klekotka [b6]; Aiyav.Nirula [b6]; Elsaid, Olivia [oelsaid@deloitte.com]; Robert Jan Benschoep [b6]; Lei Shen [b6]
Subject: Re: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Hi Lisa,

That's fine. Perhaps you and Karen could circulate some brief details of the Bayesian model framework and associated priors for each outcome measure you are envisaging? --- I think that would help in moving things along.

Looking forward to discussing,

Michael

From: LaVange, Lisa M [b6]
Sent: Thursday, May 21, 2020 1:34 PM

APAR0000005312-2444037

To: Michael Hughes; Proschan, Michael (NIH/NIAID) [E]; Eron, Joseph J Jr; Adam, Stacey (FNIH) [T]; currier.judith; Eric Hughes; Sandeep Menon; read.sarah; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; smith.davey; edaar@lundquist.org; chew.kara; Wohl, David A; Fischer, William A. II; javan.arzhang; Roa, Jhoanna; [b6] kim.peter; li.jonathan; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Kozak, Marina (OS/ASPR/BARDA)

Cc: DeMarcus, Forrest; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; roa.jhoanna; Smith, David; Paul Klekotka; Ajay Nirula; Elsaid, Olivia; Robert Jan Benschop; Lei Shen

Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Thanks, Michael. I believe it is premature to submit the protocol to your internal review committee. My take-away from yesterday's meeting was that the next step would be for the subgroup of statisticians to meet to discuss the simulations required for the revised trial design. The proposed revisions to the design are needed, in my opinion, to give us the type of flexible, fast-moving master protocol we need to screen a large amount of monoclonal antibodies. But we need to work out some of the design details, so let's have that next meeting as planned. Hoping we can schedule it for some time tomorrow and will work with Stacey to find a time.

Lisa

From: Michael Hughes [b6]

Sent: Thursday, May 21, 2020 11:03 AM

To: Proschan, Michael (NIH/NIAID) [E] [b6]; LaVange, Lisa M [b6]; Eron, Joseph J Jr [b6]; Adam, Stacey (FNIH) [T] [b6]; currier.judith [b6]; Eric Hughes [b6]; Sandeep Menon [b6]; read.sarah [b6]; Price, Dionne (FDA/CDER) [b6]; Rubin, Daniel B. (FDA/CDER) [b6]; Farley, John (FDA/CDER) [b6]; Karen Lynn Price [b6]; smith.davey [b6]; Wohl, David A [b6]; Fischer, William A. II [b6]; javan.arzhang [b6]; Roa, Jhoanna [b6]; kim.peter <[b6]>; li.jonathan [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]; Kozak, Marina (OS/ASPR/BARDA) [b6]

Cc: DeMarcus, Forrest [b6]; Tountas, Karen (FNIH) [T] [b6]; Wachtel, Jonathan <jwachtel@deloitte.com>; Elizabeth Kim <elkim@deloitte.com>; Parker, Ashley (NIH/OD) [E] [b5]; roa.jhoanna [b6]; Smith, David [b6]; Paul Klekotka [b6]; Ajay Nirula [b6]; Elsaid, Olivia <oelsaid@deloitte.com>; Robert Jan Benschop [b6]; Lei Shen [b6]

Subject: Re: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Hi All:

The ACTG team was hoping to submit the A5401 protocol tomorrow to the NIAID Clinical Science Review Committee for their review. The protocol design uses standard (widely-used) statistical methods for interim and final analyses but we received the feedback (attached) from ACTIV about moving to fully use Bayesian methods, so wanted to respond and get thoughts back as this is a substantial change --- and would mean that we would not be able to send for CSRC tomorrow.

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Sent: Thursday, May 21, 2020 8:52 AM
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Cc: DeMarcus, Forrest; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; roa.jhoanna; Smith, David; Paul Klekotka; Ajay Nirula; Elsaid, Olivia; Robert Jan Benschop; Lei Shen
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I think t [b5]
[b5]

Mike.

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[b6]; Eric Hughes [b6]; Sandeep Menon
[b6]; Proschan, Michael (NIH/NIAID) [E] [b6]; Read, Sarah
(NIH/NIAID) [E] [b6]; Price, Dionne (FDA/CDER) [b6]; Rubin, Daniel B.
(FDA/CDER) [b6]; Farley, John (FDA/CDER) [b6]; Karen Lynn Price

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Wohl, David A

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>; Fischer, William A. II

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Cc: DeMarcus, Forrest

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Tountas, Karen (FNIH) [T]

b6

; Wachtel, Jonathan

<jwachtel@deloitte.com>; Elizabeth Kim <elkim@deloitte.com>; Parker, Ashley (NIH/OD) [E]

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Elsaid, Olivia <oelsaid@deloitte.com>; Robert Jan

Benschop

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; Lei Shen

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Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

This seems reasonable to me

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Lisa

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Judy Currier

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Eric Hughes

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LaVange, Lisa M

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>; Sandeep Menon

b6

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>; Read, Sarah

(NIH/NIAID) [E]

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; Rubin, Daniel B.

(FDA/CDER)

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>; Karen Lynn Price

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Tountas, Karen (FNIH) [T]

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; Wachtel, Jonathan

<jwachtel@deloitte.com>; Elizabeth Kim <elkim@deloitte.com>; Parker, Ashley (NIH/OD) [E]

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Jhoanna Roa

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My question

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b5

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Joe Eron MD

Professor of Medicine

University of North Carolina at Chapel Hill

School of Medicine

APAR0000005312-2444037

jeron@med.unc.edu
919 843 2722

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Wednesday, May 20, 2020 5:42 PM
To: Judy Currier [b6]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Sandeep Menon [b6]; Proschan, Michael (NIH/NIAID) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Price, Dionne (FDA/CDER) [b6]; Rubin, Daniel B. (FDA/CDER) [b6]; Farley, John (FDA/CDER) [b6]; Karen Lynn Price [b6]; Wohl, David A [b6]; Fischer, William A. II [b6]; Eron, Joseph J Jr [b6]; Javan, Arzhang (NIH/NIAID) [E] [b6]; Roa, Jhoanna [b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Jonathan Li [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]; Kozak, Marina (OS/ASPR/BARDA) [b6];
Cc: DeMarcus, Forrest [b6]; Tountas, Karen (FNIH) [T] [b6]; Wachtel, Jonathan <jwachtel@deloitte.com>; Elizabeth Kim <elkim@deloitte.com>; Parker, Ashley (NIH/OD) [E] [b6]; Jhoanna Roa [b6]; Eron, Joseph J Jr [b6]; Smith, David [b6]; Paul Klekotka [b6]; Ajay Nirula [b6]; Elsaid, Olivia <oelsaid@deloitte.com>; Robert Jan Benschop [b6]; Lei Shen [b6]
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Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [b6] Mobile: [b6]

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/21/2020 7:05:20 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [b6]; Eisner, Mark [b6]; Gottesdiener, Keith [b6]; Hughes, Eric [b6]; Judy Carrier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [elkim@deloitte.com]; LaVange, Lisa [b6]; Levy, Elliot [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [b6]; Peppercorn, Amanda [b6]; Poole, Mike [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coll]; Amanda Peppercorn [b6]; Garner, Carl [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Burgess, Timothy [b6]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-roosenbey]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [b6]; Jansen, Kathrin [b6]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [b6]; Biggs, Mary [b6]; Butcher, Tina [b6]

Demarcus [b6]; Macone, Erin [b6]; Melencio, Cheryl (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH)
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan
 [jwachtel@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Alvarez, Rosa [rosalvarez@deloitte.com];
 Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [b6]; Rose
 Li Central Account [FNIH@roseliassociates.com]; Anderson, Margaret [marganderson@deloitte.com]; Lucas
 Smalldon [b6]; Stratton, Benjamin [bstratton@DELOITTE.com];
 [b6]; Mollica, Linda /US [b6]; Qashu, Felicia (NIH/OD) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Goff, David (NIH/NHLBI) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Rubin, Daniel B. (FDA/CDER)
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary
 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]

Subject: ACTIV TX-Clinical Working Group Meeting #8

Location: [b6]

Start: 5/28/2020 5:00:00 PM

End: 5/28/2020 6:00:00 PM

Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]

Optional Attendees: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin [b6]; Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] [b6]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]

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[b6]; Biggs, Mary [b6]; Butcher, Tina [b6];
Demarcus [b6]; Macone, Erin [b6]; Melencio, Cheryl (FNIH) [T]
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[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4b79577e2aa8d1-jamesst]; Wachtel, Jonathan
[jwachtel@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Alvarez, Rosa [rosalvarez@deloitte.com];
Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group
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Smalldon [b6]; Stratton, Benjamin [bstratton@DELOITTE.com];
[b6]; Mollica, Linda /US [b6] Qashu, Felicia (NIH/OD) [E]
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(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Hoots, W. Keith
(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]

Subject: ACTIV TX-Clinical Working Group Meeting #8
Attachments: ACTIV_TX-Clinical_Working Group Meeting Guide_20200528.pdf
Location: [b6]

Start: 5/28/2020 5:00:00 PM
End: 5/28/2020 6:00:00 PM
Show Time As: Busy

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]

Optional Attendees: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; **b6**; Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; **b6**; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Hoots, W. Keith (NIH/NHLBI) [E]; Mensah, George (NIH/NHLBI) [E]; Kiley, James (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]

Dear TX-Clinical WG,

Please find attached the slides for the meeting today. We will have some slight updates on the mAb criteria to discuss, but otherwise these are what we will use to review.

Thanks,

Stacey

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From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
Sent: 5/21/2020 9:09:35 PM
To: Bascles, Lionel [b6]; Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [b6]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers, Betsy [b6]; Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshov, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshovj]; Garner, Carlos [b6]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Mensah, George (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura [b6]; Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Vincent, Mike [b6]; Weinmann, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang]
CC: Wachtel, Jonathan [jwachtel@deloitte.com]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [b6]; Jansen, Kathrin [b6]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [b6]; Criffield, Robin [b6]; Hamilton, Nancy [b6]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Minnich, Beth [b6]; Mueller-Reichenstein, Petra [b6]; Pico, Dianna (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=471cb6a63c8846a69073e1e968f3964c-picodf]; Quadros, Nora [b6]; Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Hill, Zoe (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [marganderson@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Carluccio, Dana [b6]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny [b6]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [b6]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Santos, Michael (FNIH) [T]

[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuvevsson, Nancy
b6]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]

Subject: Summary and action items - CT Capacity WG meeting #10

Attachments: Clinical_Trial_Capacity_Working_Group_Meeting_10_Final.pdf

Dear Clinical Trial Capacity Working Group Members,

Attached is the summary and action items for meeting #10 (May 15, 2020) of the full working group. The next full working group meeting is scheduled for Friday, May 22 at 9 am eastern time USA.

Thanks!

Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health

b6 | fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



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From: Culp, Michelle (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4E38FA37E0424217AA0A283CBA9E5098-MCULP]
Sent: 5/21/2020 9:58:09 PM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadbois!]
Subject: RE: Slides for ACTIV TX-Clinical Working Group Meeting #7

Yes and yes.

Let's just do a Skype call.

From: Gadbois, Ellen (NIH/OD) [E] [b6]
Sent: Thursday, May 21, 2020 5:55 PM
To: Culp, Michelle (NIH/OD) [E] [b6]
Subject: RE: Slides for ACTIV TX-Clinical Working Group Meeting #7

Can we chat around 8:30 tomorrow a.m.? And I think we should send LT some kind of short alert tomorrow afternoon about some directives that may not be met cause ICs are doing their own thing anyway, unless they want to intervene with a strong directive. Personally I think this partnership should readjust to go wherever it looks like it can be most helpful and try not to bring sailed ships back, but I tend to be pessimistic about success of central control.

From: Culp, Michelle (NIH/OD) [E] [b6]
Sent: Thursday, May 21, 2020 4:24 PM
To: Gadbois, Ellen (NIH/OD) [E] [b6]
Subject: RE: Slides for ACTIV TX-Clinical Working Group Meeting #7

No, so thanks for sending. I will request Stacey and Mike to add me to the Therapeutics Clinical and Vaccine WG calls. Do you want to chat this evening or tomorrow morning?

From: Gadbois, Ellen (NIH/OD) [E] [b6]
Sent: Thursday, May 21, 2020 4:01 PM
To: Culp, Michelle (NIH/OD) [E] [b6]
Subject: FW: Slides for ACTIV TX-Clinical Working Group Meeting #7

Did you get this in time to join today? I did. You should try to follow this group. They mostly talked about their plans for a master protocol for the mAbs and I'm sure you would get more out of the details. But I have some observations (not urgent to discuss).

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Thursday, May 21, 2020 12:44 PM
To: Bozette, Sam (NIH/NCATS) [E] [b6]; Butterton, Joan [b6]; De Claro, R. Angelo (FDA/CDER) [b6]; Draghia-Akli, Ruxandra [b6]; Eisner, Mark [b6]; Gottesdiener, Keith [b6]; Hughes, Eric [b6]; Judy Currier [b6]; Kim, Elizabeth [b6]; LaVange, Lisa [b6]; Levy, Elliot [b6]; Mellors, John W [b6]; Menon, Sandeep [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Patel, Naimish [b6]; Peppercorn, Amanda [b6]; Poole, Mike [b6]; Proschan, Michael (NIH/NIAID) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Santos, Michael (FNIH) [T] [b6]; Shen, Yuan Li (FDA/CDER) [b6]; Stein, Peter (FDA/CDER) [b6]; Wholley, David (FNIH) [T] [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [b6]; Collins, Sylva (FDA/CDER) [b6]; Amanda Peppercorn [b6]; Garner, Carl [b6]

[b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6]; Koroshetz, Walter (NIH/NINDS) [E] [b6]; Burgess, Timothy [b6] Reineck, Lora (NIH/NHLBI) [E] [b6] Aggarwal, Neil (NIH/NHLBI) [E] [b6] Rosenberg, Yves (NIH/NHLBI) [E] [b6]; Brown, Jeremy (NIH/NINDS) [E] [b6] Gadbois, Ellen (NIH/OD) [E] [b6]
Cc: Colvis, Christine (NIH/NCATS) [E] [b6] Desrosiers, Betsy [b6] Jansen, Kathrin [b6] Kurilla, Michael (NIH/NCATS) [E] [b6] Lowy, Douglas (NCI) [b6]; Young, John [b6] Biggs, Mary [b6] Butcher, Tina [b6] Demarcus [b6] Macone, Erin [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Salathin, Carla [b6]; Tountas, Karen (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]; James, Stephanie (FNIH) [T] [b6] Wachtel, Jonathan <jwachtel@deloitte.com>; Tolman, Brett <btolman@deloitte.com>; Alvarez, Rosa <rosalvarez@deloitte.com>; Gonzalez, Nina <ningonzalez@deloitte.com>; Dana Carluccio <dana.carluccio@roseliassociates.com>; Rose Li Central Account <FNIH@roseliassociates.com>; Anderson, Margaret <marganderson@deloitte.com>; Lucas Smalldon [b6] Stratton, Benjamin <bstratton@DELOITTE.com>; [b6] Mollica, Linda /US <[b6]> Qashu, Felicia (NIH/OD) [E] [b6]; Patterson, Amy (NIH/NHLBI) [E] [b6]; Goff, David (NIH/NHLBI) [E] [b6]; Rubin, Daniel B. (FDA/CDER) [b6]

Subject: Slides for ACTIV TX-Clinical Working Group Meeting #7

Dear ACTIV TX-Clinical WG,

Looking forward to seeing you all soon at the meeting. Please find attached the slides for the meeting.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [b6] Mobile: [b6]

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From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
Sent: 5/21/2020 10:23:24 PM
To: Vincent, Mike [b6]; Bascles, Lionel [b6]; Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [b6]; Desrosiers, Betsy [b6]; Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshov, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshovj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5b9c808eca8f6f-nayaksu]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura [b6]; Srinivasan, Badhri [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wachtel, Jonathan [jwachtel@deloitte.com]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]
CC: Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Kenny, Dermot [b6]; Weinmann, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang]; Mensah, George (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Garner, Carlos [b6]; Denny, Joshua (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cdb4626dabbb45aa8b8e5d21169344e6-dennyjc]; Reid, Nancy (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=baa8b238107d4c39822dbe4459ff0089-reidnc]; Gebo, Kelly (NIH/OD) [G] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=009cf99ae63f4f71b5b1204a73ded609-geboka]; Moschetti, Justin (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=194d297d48db4292821d286fa89badce-moschettij]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [b6]; Jansen, Kathrin [b6]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [b6]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [marganderson@deloitte.com]; Carluccio, Dana [b6]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny [b6]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [b6]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveson, Nancy [b6]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Criffield, Robin [b6]; Hamilton, Nancy [b6]; Minnich, Beth [b6]; Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Stratton, Benjamin [bstratton@DELOITTE.com]; Tolman, Brett [btolman@deloitte.com]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Jintanat Ananworanich [b6]

Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting

Attachments: Clinical Trial Capacity Working Group Meeting Agenda_05222020.pdf; ACTIV Protocol Tracker 05212020.pdf

Location: [b6]

Start: 5/22/2020 1:00:00 PM

End: 5/22/2020 2:00:00 PM

Show Time As: Tentative

Recurrence: Weekly
every Tuesday and Friday from 9:00 AM to 10:00 AM

Required Attendees: Vincent, Mike; Bascles, Lionel; Cohen, Myron; Corey, Larry; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C];

Doroshov, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; Kurilla, Mike; Nayak, Seema (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Payton, Manzine; Resnansky, Laura; Srinivasan, Badhri; Stein, Peter (FDA/CDER); Wachtel, Jonathan; Qashu, Felicia

Optional Attendees: Sizemore, Christine (NIH/FIC) [E]; Kenny, Dermot; Weinmann, Gail (NIH/NHLBI) [E]; Mensah, George (NIH/NHLBI) [E];

Garner, Carlos; Denny, Joshua (NIH/OD) [E]; Reid, Nancy (NIH/OD) [C]; Gebo, Kelly (NIH/OD) [G]; Moschetti, Justin (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Carluccio, Dana; Cheryl (FNIH) Melencio [T] [b6]; Francis Collins; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH); Tuveson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Minnich, Beth; Rebecca (NIH/NCATS) Katz [E] [b6]; Stratton, Benjamin; Tolman, Brett; Davey, Victoria; Jintanat Ananworanich

Dear Colleagues, Attached is the Agenda. Please note that we will be hearing from the All of Us program and how they might be useful for implementing ACTIV protocols. In addition, per a request from Tuesday's meeting, attached is the ACTIV Protocol Quick Reference Tracker – thanks to Jonathan and his colleagues for creating this! At present there are three ACTIV protocols, all in the treatment category. CTC Recommendations Committees have been established for the ACTIV-1 and ACTIV-2 protocols to-date and integration with the protocol development and lead network operations teams will take place in the very near future. Best regards, Karen

ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines

Dear Clinical Trial Capacity Working Group members,

In anticipation of this working group making rapid progress on identified action items and other activities, the co-chairs have agreed that it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify areas of need, and to determine next steps. We ask that you make every effort possible to join each of these meetings, but understand that at times you may have competing priorities. To place a hold on your calendar, please accept this meeting invite with a response; later you can decline an individual meeting if you have a conflict.

An agenda and other meeting materials, as needed, will be distributed prior to each call.

With best regards,
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health

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From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
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To: Bascles, Lionel [b6]; Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [b6]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers, Betsy [b6]; Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshow, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshoj]; Garner, Carlos [b6]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Mensah, George (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura [b6]; Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Vincent, Mike [b6]; Wachtel, Jonathan [jwachtel@deloitte.com]; Weinmann, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang]
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Subject: CTC WG call #11 agenda and ACTIV protocol tracker

Attachments: Clinical Trial Capacity Working Group Meeting Agenda_05222020.pdf; ACTIV Protocol Tracker 05212020.pdf

Dear Colleagues,

Attached is the Agenda for the next Clinical Trial Capacity WG meeting, scheduled for tomorrow, Friday May 22, at 9 am eastern US time. Please note that we will be hearing from the All of Us program and how they might be useful for implementing ACTIV protocols.

In addition, per a request from Tuesday's meeting, attached is the ACTIV Protocol Quick Reference Tracker – thanks to Jonathan and his colleagues for creating this! At present there are three ACTIV protocols, all in the treatment category. CTC Recommendations Committees have been established for the ACTIV-1 and ACTIV-2 protocols to-date and integration with the protocol development and lead network operations teams will take place in the very near future.

Best regards,
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health

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11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



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Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [b6]; Jansen, Kathrin [b6]; Lowy, Douglas (NCI) [b6] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [b6]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [marganderson@deloitte.com]; 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Anderson, Margaret [marganderson@deloitte.com]; Carluccio, Dana [b6]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [b6]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [marganderson@deloitte.com]; Carluccio, Dana [b6]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [b6]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; 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Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting

Attachments: Clinical Trial Capacity Working Group Meeting Agenda_05222020.pdf; ACTIV Protocol Tracker 05212020.pdf

Location: [b6]

Start: 5/22/2020 1:00:00 PM

End: 5/22/2020 2:00:00 PM

Show Time As: Tentative

Recurrence: Weekly

every Tuesday and Friday from 9:00 AM to 10:00 AM

Required Attendees: Vincent, Mike; Bascles, Lionel; Cohen, Myron; Corey, Larry; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C];

Doroshov, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; Kurilla, Mike; Nayak, Seema (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Payton, Manzone; Resnansky, Laura; Srinivasan, Badhri; Stein, Peter (FDA/CDER); Wachtel, Jonathan; Qashu, Felicia

Optional Attendees: Sizemore, Christine (NIH/FIC) [E]; Kenny, Dermot; Weinmann, Gail (NIH/NHLBI) [E]; Mensah, George (NIH/NHLBI) [E];

Garner, Carlos; Denny, Joshua (NIH/OD) [E]; Reid, Nancy (NIH/OD) [C]; Gebo, Kelly (NIH/OD) [G]; Moschetti, Justin (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Carluccio, Dana; Cheryl (FNIH) Melencio [T] [b6]; Francis Collins; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH); Tuveson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Minnich, Beth; Rebecca (NIH/NCATS) Katz [E] [b6]; Stratton, Benjamin; Tolman, Brett; Davey, Victoria; Jintanat Ananworanich

Dear Colleagues, Attached is the Agenda. Please note that we will be hearing from the *All of Us* program and how they might be useful for implementing ACTIV protocols. In addition, per a request from Tuesday's meeting, attached is the ACTIV Protocol Quick Reference Tracker – thanks to Jonathan and his colleagues for creating this! At present there are three ACTIV protocols, all in the treatment category. CTC Recommendations Committees have been established for the ACTIV-1 and ACTIV-2 protocols to-date and integration with the protocol development and lead network operations teams will take place in the very near future. Best regards, Karen

ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines

Dear Clinical Trial Capacity Working Group members,

In anticipation of this working group making rapid progress on identified action items and other activities, the co-chairs have agreed that it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify areas of need, and to determine next steps. We ask that you make every effort possible to join each of these meetings, but

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understand that at times you may have competing priorities. To place a hold on your calendar, please accept this meeting invite with a response; later you can decline an individual meeting if you have a conflict.

An agenda and other meeting materials, as needed, will be distributed prior to each call.

With best regards,
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health

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From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
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To: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Bascles, Lionel [b6]; Cohen, Myron [b6]; Corey, Larry [b6]; Desrosiers, Betsy [b6]; Dickens, Jim (NIH/NCATS) [C] [b6]; Doroshov, James (NIH/NCI) [E] [b6]; Goff, David (NIH/NHLBI) [E] [b6]; Kurilla, Michael (NIH/NCATS) [E] [b6]; Nayak, Seema (NIH/NIAID) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Payton, Manizhe (NIH/NIAID) [E] [b6]; Resnansky, Laura [b6]; Srinivasan, Badhri [b6]; Stein, Peter (FDA/CDER) [b6]; Wachtel, Jonathan [jwachtel@deloitte.com]; Qashu, Felicia (NIH/OD) [E] [b6]; Vincent, Mike [b6]
CC: Colvis, Christine (NIH/NCATS) [E] [b6]; Jansen, Kathrin [b6]; Lowy, Douglas (NCI) [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Young, John [b6]; Adam, Stacey (FNIH) [T] [b6]; Anderson, Margaret [marganderson@deloitte.com]; Carluccio, Dana [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Gonzalez, Nina [ningonzalez@deloitte.com]; Heaton, Penny [b6]; James, Stephanie (FNIH) [T] [b6]; Li, Rose [b6]; Menetski, Joseph (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]; Tuveson, Nancy [b6]; Wholley, David (FNIH) [T] [b6]; Criffield, Robin [robin_criffield@med.unc.edu]; Minnich, Beth [b6]; Katz, Rebecca (NIH/NCATS) [E] [b6]; Stratton, Benjamin [bstratton@DELOITTE.com]; Tolman, Brett [btolman@deloitte.com]; Victoria Davey [b6]; Jintanat Ananworanich [b6]; Sizemore, Christine (NIH/FIC) [E] [b6]; Kenny, Dermot [b6]; Weinmann, Gail (NIH/NHLBI) [E] [b6]; Mensah, George (NIH/NHLBI) [E] [b6]; Garner, Carlos [b6]; Denny, Joshua (NIH/OD) [E] [b6]; Reid, Nancy (NIH/OD) [C] [b6]; Gebo, Kelly (NIH/OD) [G] [b6]; Moschetti, Justin (NIH/OD) [E] [b6]; Culp, Michelle (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Hughes, Eric [b6]; Hamilton, Nancy [b6]

Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting
Attachments: Clinical Trial Capacity Working Group Meeting Agenda_05222020.pdf; ACTIV Protocol Tracker 05212020.pdf
Location: [b6]

Start: 5/22/2020 1:00:00 PM
End: 5/22/2020 2:00:00 PM
Show Time As: Tentative

Recurrence: Weekly
every Tuesday and Friday from 9:00 AM to 10:00 AM

Required Attendees: Vincent, Mike; Bascles, Lionel; Cohen, Myron; Corey, Larry; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshov, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; Kurilla, Mike; Nayak, Seema (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Payton, Manizhe; Resnansky, Laura; Srinivasan, Badhri; Stein, Peter (FDA/CDER); Wachtel, Jonathan; Qashu, Felicia

Optional Attendees: Sizemore, Christine (NIH/FIC) [E]; Kenny, Dermot; Weinmann, Gail (NIH/NHLBI) [E]; Mensah, George (NIH/NHLBI) [E]; Garner, Carlos; Denny, Joshua (NIH/OD) [E]; Reid, Nancy (NIH/OD) [C]; Gebo, Kelly (NIH/OD) [G]; Moschetti, Justin (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Carluccio, Dana; Cheryl (FNIH) Melencio [T] [b6]; Francis Collins; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH); Tuveson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Minnich, Beth; Rebecca (NIH/NCATS) Katz [E] [b6]; Stratton, Benjamin; Tolman, Brett; Davey, Victoria; Jintanat Ananworanich

Dear Colleagues, Attached is the Agenda. Please note that we will be hearing from the All of Us program and how they might be useful for implementing ACTIV protocols. In addition, per a request from Tuesday's meeting, attached is the ACTIV Protocol Quick Reference Tracker – thanks to Jonathan and his colleagues for creating this! At present there are three ACTIV protocols, all in the treatment category. CTC Recommendations Committees have been established for the ACTIV-1 and ACTIV-2 protocols to-date and integration with the protocol development and lead network operations teams will take place in the very near future. Best regards, Karen

ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines

Dear Clinical Trial Capacity Working Group members,

In anticipation of this working group making rapid progress on identified action items and other activities, the co-chairs have agreed that it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify areas of need, and to determine next steps. We ask that you make every effort possible to join each of these meetings, but understand that at times you may have competing priorities. To place a hold on your calendar, please accept this meeting invite with a response; later you can decline an individual meeting if you have a conflict.

An agenda and other meeting materials, as needed, will be distributed prior to each call.

With best regards,
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/21/2020 11:37:18 PM
To: Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [b6]; Keith Gottesdiener [b6]; Elliott Levy [b6]; Wung, Peter /US [b6]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [b6]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bafd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Rose Li Central Account [FNIH@roseliassociates.com]
Subject: Initial Follow-up to ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #12
Attachments: ACTIV_Therapeutics-Clinical_Agent Prioritization Subgroup_21May2020_Key Takeaways.pdf

Dear TX-Clinical Agent Prioritization Subgroup,

Please find attached the initial follow-up to today's meeting. High level summary and action items are included, as well as a list of the members of the sub-teams for review. Please take a look and let me know if you would like to move sub-teams or be assigned to one.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
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11400 Rockville Pike, Suite 600, North Bethesda, MD 20852

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/22/2020 12:00:08 AM
To: Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Sandeep Menon [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proschan]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f29042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price [b6]; [b6]; Eron, Joe [b6]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; [b6] Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Jonathan Li [b6] Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eedb7-Gilbert.Mar]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]
CC: Demarcus [b6] Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa [b6]; Eron, Joseph J Jr [b6] Smith, David [b6] Paul Klekotka [b6] Ajay Nirula [b6] Elsaid, Olivia [oelsaid@deloitte.com]; Robert Jan Benschop [b6] Lei Shen [b6] Chen, Helen Q. [qingchen@deloitte.com]
Subject: Notes from the ACTIV TX-Clinical mAb Outpatient WT Meeting-3
Attachments: ACTIV_Therapeutics-Clinical_ACTIV TX-Clinical mAb Outpatient WT Meeting-3_20May2020_Key Takeaways.pdf; Statistical Considerations - Proschan.docx

Dear ACTIV TX-Clinical mAb Outpatient WT,

Please find the notes from last night's writing team meeting for the group's reference. Please note the action items for follow up and the bolded text actions and decisions.

In addition, as requested, I am circulated the document of Statistical Considerations that Mike Proschan put together for ACTIV-1, the large Phase 3.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

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From: Eron, Joseph J Jr [b6]
Sent: 5/22/2020 1:17:21 AM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Sandeep Menon [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price [b6]
[b6] Wohl, David A [b6]; Fischer, William A. II [b6]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; [b6] Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Jonathan Li [b6] Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]
CC: DeMarcus, Forrest [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jhoanna Roa [b6]; Smith, David [b6] Paul Klekotka [b6] Ajay Nirula [b6] Elsaid, Olivia [oelsaid@deloitte.com]; Robert Jan Benschop [b6]; Lei Shen [b6]; Chen, Helen [qingchen@deloitte.com]
Subject: RE: Notes from the ACTIV TX-Clinical mAb Outpatient WT Meeting-3
Attachments: ACTIV_Therapeutics-Clinical_ACTIV TX-Clinical mAb Outpatient WT Meeting-3_20May2020_Key TakeawaysJE.pdf

Stats insight super informative

For the summary I think there are some decisions that we made – that were supported by the group

My comments are attached in the PDF

Joe Eron MD
Professor of Medicine
University of North Carolina at Chapel Hill
School of Medicine

[b6]

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Thursday, May 21, 2020 8:00 PM
To: Judy Currier [b6]; Eric Hughes [b6]; LaVange, Lisa M

[b6] Sandeep Menon [b6]; Proschan, Michael (NIH/NIAID) [E]
[b6] Read, Sarah (NIH/NIAID) [E] [b6]; Price, Dionne (FDA/CDER)
[b6]; Rubin, Daniel B. (FDA/CDER); [b6] Farley, John (FDA/CDER)
[b6]; Karen Lynn Price [b6]
[b6] Wohl, David A
[b6]; Fischer, William A. II [b6]; Eron, Joseph J Jr
[b6]; Javan, Arzhang (NIH/NIAID) [E] [b6]; Roa, Jhoanna [b6]
[b6] Kim, Peter (NIH/NIAID) [E] [b6]; Jonathan Li [b6]
Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]; Kozak, Marina (OS/ASPR/BARDA)
[b6]
Cc: DeMarcus, Forrest <[b6]> Tountas, Karen (FNIH) [T] [b6]; Wachtel, Jonathan
<jwachtel@deloitte.com>; Elizabeth Kim <elkim@deloitte.com>; Parker, Ashley (NIH/OD) [E] [b6]
Jhoanna Roa [b6]; Eron, Joseph J Jr [b6]; Smith, David
[b6]; Paul Klekotka [b6]; Ajay Nirula [b6]; Elsaid,
Olivia <oelsaid@deloitte.com>; Robert Jan Benschop [b6]; Lei Shen [b6]
Chen, Helen Q. <hqingchen@deloitte.com>

Subject: Notes from the ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Dear ACTIV TX-Clinical mAb Outpatient WT,

Please find the notes from last night's writing team meeting for the group's reference. Please note the action items for follow up and the bolded text actions and decisions.

In addition, as requested, I am circulated the document of Statistical Considerations that Mike Proschan put together for ACTIV-1, the large Phase 3.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
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Sent: 5/22/2020 2:30:56 AM
To: Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [b6]; Keith Gottesdiener [b6]; Elliott Levy [b6]; Wung, Peter /US [b6]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [b6]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bafd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Rose Li Central Account [FNIH@roseliassociates.com]; Chen, Helen Q. [qingchen@deloitte.com]
Subject: ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #13
Location: [b6]
Start: 5/28/2020 4:00:00 PM
End: 5/28/2020 5:00:00 PM
Show Time As: Tentative

Required Attendees: Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E]
Optional Attendees: Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; [b6]; Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] [b6]; Rose Li Central Account; Chen, Helen Q.

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/22/2020 2:30:59 AM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Ruxandra Draghia-Akli [b6]; Naimish Patel [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [b6]; Keith Gottesdiener [b6]; Elliott Levy [b6]; Wung, Peter /US [b6]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [b6]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]

Subject: Canceled: ACTIV TX-Clinical Agent Prioritization- mAb Subteam Meeting

Location: [b6]

Start: 5/28/2020 4:00:00 PM

End: 5/28/2020 5:00:00 PM

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Required Attendees: Read, Sarah (NIH/NIAID) [E]; Eric Hughes; Amanda Peppercorn; Breuer, Sebastian; Martin, Flavius; Andrew Charles Adams; John Mellors; Marovich, Mary (NIH/NIAID) [E]; Judy Currier; Tressler, Randall (NIH/NIAID) [E]; Smith, David
Optional Attendees: Elizabeth Kim; Chen, Helen Q.; Payton, Natalie; Andrew Para; GMM76@pitt.edu; Dana Carluccio; Lucas Smalldon; Rose Li Central Account

Dear ACTIV TX-Clinical Agent Prioritization team,

Thank you all for your responses. We will be converting this meeting into a mAb Subteam meeting for tomorrow in the hope of finalizing the minimal entry criteria.

Thank you all for your flexibility and understanding.

Stacey

APAR0000020415

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/22/2020 2:30:59 AM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [b6] Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [b6] Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [b6] Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [b6]; Keith Gottesdiener [b6]; Elliott Levy [b6]; Wung, Peter /US [b6] Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [b6]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla [b6] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bafd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Rose Li Central Account [FNIH@roseliassociates.com]; Chen, Helen Q. [qingchen@deloitte.com]

Subject: ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #13

Location: [b6]

Start: 5/28/2020 4:00:00 PM

End: 5/28/2020 5:00:00 PM

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Required Attendees: Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E]

Optional Attendees: Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; [b6] Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E]; [b6] Rose Li Central Account; Chen, Helen Q.

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From: Menon, Sandeep M [b6]
Sent: 5/22/2020 11:43:57 AM
To: Karen Lynn Price [b6]; Michael Hughes [b6]; LaVange, Lisa M [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Eron, Joseph J Jr [b6]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; smith.davey [b6]; Wohl, David A [b6]; Fischer, William A. II [b6]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; LHosey@s-3.com; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; li.jonathan [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eedb7-Gilbert.Mar]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]
CC: DeMarcus, Forrest [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; roa.jhoanna [b6]; Smith, David [b6]; Paul Klekotka [b6]; Ajay Nirula [b6]; Elsaid, Olivia [oelsaid@deloitte.com]; Robert Jan Benschop [b6]
Subject: Re: [EXTERNAL] Re: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Thanks Karen. It would be tricky to have "informative" prior incorporated as the data is still evolving. I am assuming we will do simulations using "non-informative" priors and incorporate flexibility in the protocol as the data evolves. There are too many variables here – evolving SOC, recruitment rate, correlation between endpoints, etc....

From: Karen Price [b6]
Date: Friday, May 22, 2020 at 12:07 AM
To: Michael Hughes [b6]; "LaVange, Lisa M" [b6]; "Proschan, Michael (NIH/NIAID) [E]" [b6]; "Eron, Joseph J Jr" [b6]; "Adam, Stacey (FNIH) [T]" [b6]; "currier.judith" [b6]; Eric Hughes [b6]; Sandeep Menon [b6]; "read.sarah" [b6]; "Dionne.Price@fda.hhs.gov" [b6]; "Rubin, Daniel B. (FDA/CDER)" [b6]; "Farley, John (FDA/CDER)" [b6]; "smith.davey" [b6]; "chew.kara" [b6]; "Wohl, David A" [b6]

[REDACTED] b6 >, "Fischer, William A. II" [REDACTED] b6 "javan.arzhang"
[REDACTED] b6 "Roa, Jhoanna" [REDACTED] b6 [REDACTED] b6
"kim.peter" [REDACTED] b6 "li.jonathan" [REDACTED] b6 "Marks, Gilbert (OS/ASPR/BARDA)
(CTR)" [REDACTED] b6 "Kozak, Marina (OS/ASPR/BARDA)" [REDACTED] b6 >
Cc: "DeMarcus, Forrest" [REDACTED] b6 "Tountas, Karen (FNIH) [T]" [REDACTED] b6
"Wachtel, Jonathan" <jwachtel@deloitte.com>, Elizabeth Kim <elkim@deloitte.com>, "Parker, Ashley
(NIH/OD) [E]" [REDACTED] b6 "roa.jhoanna" [REDACTED] b6 "Smith, David"
[REDACTED] b6, Paul Klekotki [REDACTED] b6, Ajay Nirula [REDACTED] b6
"Elsaid, Olivia" <oelsaid@deloitte.com>, Robert Jan Benschoop [REDACTED] b6, Lei Shen
[REDACTED] b6

Subject: Re: [EXTERNAL] Re: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Thanks Lisa and Michael.

Working now to put together more details on the modeling and developing a simulation plan. We look forward to discussing in our stats meetings soon. Whether we end up with Bayesian or frequentist approach, simulation of this design will be required in order to better understand the operating characteristics.

I do think it is important we keep in mind that for a master protocol such as this, the specific model used and associated priors will necessarily change over time. So the intent would be to put the basic framework of the model into the master protocol, but specify the model, agent's specific sample size, and operating characteristics assessed via simulation in the associated agent's appendix. One advantage of this is that in order to navigate through these many agents efficiently and effectively we necessarily need to learn over time and formally incorporate that learning into our modeling. For example, we will learn more over time about the relationship between the symptomatic endpoints/viral endpoints/clinical endpoint (hospitalization/er visit/death) and that learning needs to be incorporated into future agent's modeling, which should also lower sample size and improve precision/decision making across these agents. It is presently unclear to me how we can effectively evaluate several agents / borrow placebo / incorporate prior knowledge we will gain over time / etc without a Bayes approach, but I look forward to discussing in our stats meetings.

Thanks,
Karen

From: Michael Hughes [REDACTED] b6
Date: Thursday, May 21, 2020 at 12:54 PM
To: "LaVange, Lisa M" <lisa.lavange@unc.edu>, "Proschan, Michael (NIH/NIAID) [E]"
[REDACTED] b6 >, "Eron, Joseph J Jr" [REDACTED] b6 "Adam, Stacey (FNIH) [T]"
[REDACTED] b6, "currier.judith" [REDACTED] b6 Eric Hughes [REDACTED] b6
Sandeep Menon [REDACTED] b6 "read.sarah" [REDACTED] b6 "Price, Dionne
(FDA/CDER)" [REDACTED] b6 "Rubin, Daniel B. (FDA/CDER)" [REDACTED] b6
"Farley, John (FDA/CDER)" [REDACTED] b6, Karen Price [REDACTED] b6
"smith.dave" [REDACTED] b6 >, "chew.kara"
[REDACTED] b6, "Wohl, David A" [REDACTED] b6 "Fischer, William A. II"
[REDACTED] b6, "javan.arzhang" [REDACTED] b6 "Roa, Jhoanna" [REDACTED] b6
[REDACTED] b6 "kim.peter" [REDACTED] b6 "li.jonathan"
[REDACTED] b6 "Marks, Gilbert (OS/ASPR/BARDA) (CTR)" [REDACTED] b6 "Kozak, Marina
(OS/ASPR/BARDA)" [REDACTED] b6
Cc: "DeMarcus, Forrest" [REDACTED] b6 "Tountas, Karen (FNIH) [T]" [REDACTED] b6
"Wachtel, Jonathan" <jwachtel@deloitte.com>, Elizabeth Kim <elkim@deloitte.com>, "Parker, Ashley
(NIH/OD) [E]" [REDACTED] b6, "roa.jhoanna" [REDACTED] b6 "Smith, David"

[b6], Paul Klekotka [b6] Ajay Nirula [b6],
"Elsaid, Olivia" <oelsaid@deloitte.com>, Robert Jan Benschop [b6], Lei Shen
[b6] >
Subject: [EXTERNAL] Re: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

EXTERNAL EMAIL: Use caution before replying, clicking links, and opening attachments.

Hi Lisa,

That's fine. Perhaps you and Karen could circulate some brief details of the Bayesian model framework and associated priors for each outcome measure you are envisaging? --- I think that would help in moving things along.

Looking forward to discussing,

Michael

From: LaVange, Lisa M [b6]
Sent: Thursday, May 21, 2020 1:34 PM
To: Michael Hughes; Proschan, Michael (NIH/NIAID) [E]; Eron, Joseph J Jr; Adam, Stacey (FNIH) [T]; currier.judith; Eric Hughes; Sandeep Menon; read.sarah; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; [b6] chew.kara; Wohl, David A; Fischer, William A. II; javan.arzhang; Roa, Jhoanna; [b6] kim.peter; li.jonathan; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Kozak, Marina (OS/ASPR/BARDA)
Cc: DeMarcus, Forrest; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; roa.jhoanna; Smith, David; Paul Klekotka; Ajay Nirula; Elsaid, Olivia; Robert Jan Benschop; Lei Shen
Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Thanks, Michael. I believe it is premature to submit the protocol to your internal review committee. My take-away from yesterday's meeting was that the next step would be for the subgroup of statisticians to meet to discuss the simulations required for the revised trial design. The proposed revisions to the design are needed, in my opinion, to give us the type of flexible, fast-moving master protocol we need to screen a large amount of monoclonal antibodies. But we need to work out some of the design details, so let's have that next meeting as planned. Hoping we can schedule it for some time tomorrow and will work with Stacey to find a time.

Lisa

From: Michael Hughes [b6]
Sent: Thursday, May 21, 2020 11:03 AM
To: Proschan, Michael (NIH/NIAID) [E] [b6]; LaVange, Lisa M [b6]; Eron, Joseph J Jr [b6]; Adam, Stacey (FNIH) [T] [b6]; currier.judith [b6]; Eric Hughes [b6]; Sandeep Menon [b6]; read.sarah [b6]; Price, Dionne (FDA/CDER) [b6]; Rubin, Daniel B. (FDA/CDER) [b6]; Farley, John (FDA/CDER) [b6]; Karen Lynn Price [b6]; smith.davey [b6]; chew.kara [b6]; Wohl, David A [b6]; Fischer, William A. II [b6]; javan.arzhang [b6]; Roa, Jhoanna [b6]; kim.peter [b6]; li.jonathan [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]; Kozak, Marina (OS/ASPR/BARDA) [b6]
Cc: DeMarcus, Forrest [b6]; Tountas, Karen (FNIH) [T] [b6]; Wachtel, Jonathan <jwachtel@deloitte.com>; Elizabeth Kim <elkim@deloitte.com>; Parker, Ashley (NIH/OD) [E] [b6]; [b6] Smith, David [b6]; Paul Klekotka [b6]; Ajay Nirula [b6]; Elsaid, Olivia <oelsaid@deloitte.com>; Robert Jan Benschop [b6]; Lei Shen [b6]
Subject: Re: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Hi All:

The ACTG team was hoping to submit the A5401 protocol tomorrow to the NIAID Clinical Science Review Committee for their review. The protocol design uses standard (widely-used) statistical methods for interim and final analyses but we received the feedback (attached) from ACTIV about moving to fully use Bayesian methods, so wanted to respond and get thoughts back as this is a substantial change --- and would mean that we would not be able to send for CSRC tomorrow.

I have particular concerns about the need to use the Bayesian paradigm, particularly for Phase III. For a given agent, the Phase 3 study is a fairly simple study involving evaluations for safety, clinical symptoms, and the primary outcome measure of hospitalization/death. We proposed to use standard group sequential monitoring methods which are flexible (using the Lan-DeMets approach for flexible timing of interim analyses with an O'Brien and Fleming type stopping guideline). I think the seamless phase II to phase 3 aspect of the design can be incorporated into this flexible approach by just considering the "look" at the data at the end of phase II as one "look" at the phase 3 primary outcome. This provides protection for the Type I error rate for each specific agent. We can overlay a the possibility of a simple futility rule, eg at $\geq 50\%$ enrollment, to allow stopping for lack of effect (can be justified using a Type II spending boundary, conditional power, or even a Bayesian type rule).

I think this is all quite straightforward. I worry that putting the Phase 3 trial into the Bayesian paradigm gains very little but adds complexity in terms of having to confirm that any Bayesian decision rule does protect Type I error rate for regulatory purposes, and in terms of explaining to many different companies and ultimately to a broad audience. In addition, if the study does go global, it increases the complexity of explaining to IRBs and other review groups.

I would prefer to leave Phase 3 using standard (widely used) statistical methods. I would also favor using standard methods for analysis of Phase 2 data but do agree that Bayesian analyses might also be used for the main efficacy outcome measures to provide an additional perspective in decision-making --- though the main graduation rules (eg observing an absolute 20% reduction in % positive for SARS-CoV-2 at an measurement time, and/or a 20% reduction in mean symptom duration) are straightforward and well-powered.

I would welcome feedback.

Many thanks,

Michael

From: Proschan, Michael (NIH/NIAID) [E] [b6]
Sent: Thursday, May 21, 2020 8:52 AM
To: LaVange, Lisa M; Eron, Joseph J Jr; Adam, Stacey (FNIH) [T]; currier.judith; Eric Hughes; Sandeep Menon; read.sarah; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; smith.davey; Michael Hughes; [b6]; chew.kara; Wohl, David A; Fischer, William A. II; javan.arzhang; Roa, Jhoanna; [b6] kim.peter; li.jonathan; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Kozak, Marina (OS/ASPR/BARDA)
Cc: DeMarcus, Forrest; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; roa.jhoanna; Smith, David; Paul Klekotka; Ajay Nirula; Elsaid, Olivia; Robert Jan Benschop; Lei Shen
Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

I think the question is whether we could stop early for efficacy as well as stopping early for futility. That could certainly be incorporated if you think there is a realistic possibility of crossing an efficacy boundary after only 50 people. At the halfway point, the O'Brien-Fleming-like spending function boundary for the z-score is close to 3, so you would have to see a very large z-score to stop that early for efficacy.

Mike.

From: LaVange, Lisa M [b6]
Sent: Thursday, May 21, 2020 7:53 AM
To: Eron, Joseph J Jr [b6]; Adam, Stacey (FNIH) [T] [b6]; Judy Currier [b6]; Eric Hughes [b6]; Sandeep Menon [b6]; Proschan, Michael (NIH/NIAID) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Price, Dionne (FDA/CDER) [b6]; Rubin, Daniel B. (FDA/CDER) [b6]; Farley, John (FDA/CDER) [b6]; Karen Lynn Price [b6]; Wohl, David A [b6]; Fischer, William A. II [b6]; Javan, Arzhang (NIH/NIAID) [E] [b6]; Roa, Jhoanna [b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Jonathan Li [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]; Kozak, Marina (OS/ASPR/BARDA) [b6]
Cc: DeMarcus, Forrest [b6]; Tountas, Karen (FNIH) [T] [b6]; Wachtel, Jonathan [b6] <[b6]@deloitte.com>; Elizabeth Kim <elkim@deloitte.com>; Parker, Ashley (NIH/OD) [E] <[b6]>; Jhoanna Roa [b6]; Smith, David [b6]; Paul Kle [b6]; Ajay Nirula [b6]; Elsaied, Olivia <oelsaied@deloitte.com>; Robert Jan Benschop [b6]; Lei Shen [b6]
Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

This seems reasonable to me. We can define any basis that we think will be important for dropping dose arms or entire agents, having little to go on at this point in terms of what best predicts hospitalizations.

Lisa

From: Eron, Joseph J Jr
Sent: Wednesday, May 20, 2020 6:23 PM
To: Adam, Stacey (FNIH) [T] [b6]; Judy Currier [b6]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Sandeep Menon [b6]; Proschan, Michael (NIH/NIAID) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Price, Dionne (FDA/CDER) [b6]; Rubin, Daniel B. (FDA/CDER) [b6]; Farley, John (FDA/CDER) [b6]; Karen Lynn Price [b6]; Wohl, David A [b6]; Fischer, William A. II [b6]; Javan, Arzhang (NIH/NIAID) [E] [b6]; Roa, Jhoanna [b6]; Kim, Peter [b6]

(NIH/NIAID) [E] <[b6]>; Jonathan Li <[b6]>; Marks, Gilbert (OS/ASPR/BARDA) (CTR) <[b6]>; Kozak, Marina (OS/ASPR/BARDA)

[b6]
Cc: DeMarcus, Forrest <[b6]>; Tountas, Karen (FNIH) [T] <[b6]>; Wachtel, Jonathan <[b6]>; Elizabeth Kim <elkim@deloitte.com>; Parker, Ashley (NIH/OD) [E] <[b6]>; Jhoanna Roa <[b6]>; Smith, David <[b6]>; Paul Klekotka <[b6]>; Ajay Nirula <[b6]>; Elsaid, Olivia <oelsaid@deloitte.com>; Robert Jan Benschop <[b6]>; Lei Shen <[b6]>

Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Here is my question for the group – especially Michael, John and Lisa

My question is whether there could be an interim “activity” analysis similar to the futility analysis listed below – the reason I ask is we have very little longitudinal data on the quantitative viral shedding and it is possible that this endpoint would have substantial power such that 50 patients per arm could provide an antiviral answer.

- If the Phase 2 portion of the Clinical mAb protocol is used for dose finding, this may be challenging with respect to size of the trial (number of treatment arms needed and available sample size per treatment arm). In addition, it may be appropriate to establish an interim futility analysis based on change in quantitative viral shedding to allow for discontinuation of a dose after e.g. 50 rather than 110 patients, or to allow early discontinuation of high doses due to safety findings.

Joe Eron MD

Professor of Medicine

University of North Carolina at Chapel Hill

School of Medicine

b6

From: Adam, Stacey (FNIH) [T] <[b6]>

Sent: Wednesday, May 20, 2020 5:42 PM

To: Judy Currier <[b6]>; Eric Hughes <[b6]>; LaVange, Lisa M <[b6]>; Sandeep Menon <[b6]>; Proschan, Michael (NIH/NIAID) [E] <[b6]>; Read, Sarah (NIH/NIAID) [E] <[b6]>; Price, Dionne (FDA/CDER) <[b6]>; Rubin, Daniel B. (FDA/CDER) <[b6]>

Farley, John (FDA/CDER) [b6]; Karen Lynn Price [b6]
[b6]
Wohl, David A [b6]; Fischer, William A. II [b6]; Eron,
Joseph J Jr [b6]; Javan, Arzhang (NIH/NIAID) [E] [b6]; Roa,
Jhoanna [b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Jonathan
Li [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]; Kozak,
Marina (OS/ASPR/BARDA) [b6]
Cc: DeMarcus, Forrest [b6]; Tountas, Karen (FNIH) [T] [b6];
Wachtel, Jonathan <jwachtel@deloitte.com>; Elizabeth Kim <elkim@deloitte.com>; Parker, Ashley (NIH/OD)
[E] [b6]; Jhoanna Roa [b6]; Eron, Joseph J Jr
[b6]; Smith, David [b6]; Paul Klekotka
[b6]; Ajay Nirula [b6]; Elsaid, Olivia <oelsaid@deloitte.com>;
Robert Jan Benschop [b6]; Lei Shen [b6]
Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Dear mAb Outpatient WT,

The FDA team that has been working with ACTIV and sitting in on our writing team meetings for this protocol would like to offer the attached thoughts for the group's consideration on tonight's call.

Also, attaching again the updated synopsis that was discussed with the mAb Steering Committee earlier today.

Thanks,

Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: [b6] | Mobile: [b6]

Join Zoom Meeting

[b6]

Meeting ID: [b6]

Password: [b6]

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	<div>US (Tacoma)</div>
	<div>US (Houston)</div>
	<div>US (San Jose)</div>

Meeting ID:	<div>b6</div>
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Password	<div>b6</div>
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Find your local number:	<div>b6</div>
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From: Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=60008133606B4F75835D3C77C2EEADB7-GILBERT.MAR]
Sent: 5/22/2020 11:45:10 AM
To: Karen Lynn Price [b6]; Michael Hughes [b6]; LaVange, Lisa M [lisa.lavange@unc.edu]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Eron, Joseph J Jr [b6]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [b6]; Sandeep Menon [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f29042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; smith.davey [b6]; Wohl, David A [b6]; Fischer, William A. II [b6]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; [b6] Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; li.jonathan [b6]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]
CC: DeMarcus, Forrest [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; roa.jhoanna [b6]; Smith, David [b6]; Paul Klekotka [b6]; Ajay Nirula [b6]; Elsaid, Olivia [oelsaid@deloitte.com]; Robert Jan Benschop [b6]; Lei Shen [b6]
Subject: RE: [EXTERNAL] Re: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Obviously Regulatory approval is the objective. How comfortable will other sponsors be with anything other than 'traditional' measures for PhIII success? If I'm translating correctly, traditional analyses could be the default yet include Bayesian approaches as prospective ways to explore the data and perhaps evolve to in time as sponsors and regulators become more comfortable with the endpoints, the nature of the data and the alignment of the analyses, and importantly, the ability to clearly, globally communicate the results for each of the raft of compounds being assessed.

From my perspective, sponsors have been concerned about moving to total Bayesian approaches especially in view of where primary endpoints have no clear track record for demonstrating success and with a global registration strategy in mind. One consideration would be to write down mock trial results as would be communicated following a successful trial with, for example, time to event, proportions and Bayesian approaches. The strengths and weaknesses behind each (sample size, other) may help a range of sponsors, IRBs, investigators and regulatory agencies more quickly align with what is ultimately chosen. The further we move from traditional approaches, the more compelling the rationale should be. Exploratory approaches could move the field forward without jeopardizing inclusion of multiple sponsors of neutralizing abs and direct acting antivirals based on concern for how success will be determined, by others.

Best regards

APAR0000005291

Lynn

Gilbert 'Lynn' Marks, MD
Senior Advisor to BARDA, Office of the Director
Tunnell Government Services supporting the mission of:
Biomedical Advanced Research and Development Authority (BARDA)
Assistant Secretary for Preparedness and Response (ASPR)
Department of Health and Human Services (HHS)
200 C St SW
O'Neill Bldg
Washington, DC 20024

From: Karen Lynn Price [b6]
Sent: Friday, May 22, 2020 12:07 AM
To: Michael Hughes [b6]; LaVange, Lisa M [b6]; Proschan, Michael (NIH/NIAID) [E] [b6]; Eron, Joseph J Jr [b6]; Adam, Stacey (FNIH) [T] [b6]; currier.judith [b6]; Eric Hughes [b6]; Sandeep Menon [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Price, Dionne (FDA/CDER) [b6]; Rubin, Daniel B. (FDA/CDER) [b6]; Farley, John (FDA/CDER) [b6]; smith.davey [b6]; chew.kara [b6]; Wohl, David A [b6]; Fischer, William A. II [b6]; Javan, Arzhang (NIH/NIAID) [C] [b6]; Roa, Jhoanna [b6]; Kim, Peter (NIH/NIAID) [E] [b6]; li.jonathan [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]; Kozak, Marina (OS/ASPR/BARDA) [b6]
Cc: DeMarcus, Forrest <[b6]>; Tountas, Karen (FNIH) [T] [b6]; Wachtel, Jonathan <jwachtel@deloitte.com>; Elizabeth Kim <elkim@deloitte.com>; Parker, Ashley (NIH/NCI) [F] <ashley.parker@nih.gov>; roa.jhoanna [b6]; Smith, David [b6]; Paul Klekotka [b6]; Ajay Nirula [b6]; Elsaid, Olivia <oelsaid@deloitte.com>; Robert Jan Benschop [b6]; Lei Shen [b6]
Subject: Re: [EXTERNAL] Re: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Thanks Lisa and Michael.

Working now to put together more details on the modeling and developing a simulation plan. We look forward to discussing in our stats meetings soon. Whether we end up with Bayesian or frequentist approach, simulation of this design will be required in order to better understand the operating characteristics.

I do think it is important we keep in mind that for a master protocol such as this, the specific model used and associated priors will necessarily change over time. So the intent would be to put the basic framework of the model into the master protocol, but specify the model, agent's specific sample size, and operating characteristics assessed via simulation in the associated agent's appendix. One advantage of this is that in order to navigate through these many agents efficiently and effectively we necessarily need to learn over time and formally incorporate that learning into our modeling. For example, we will learn more over time about the relationship between the symptomatic endpoints/viral endpoints/clinical endpoint (hospitalization/er visit/death) and that learning needs to be incorporated into future agent's modeling, which should also lower sample size and improve precision/decision making across these agents. It is presently unclear to me how we can effectively evaluate several agents / borrow placebo / incorporate prior knowledge we will gain over time / etc without a Bayes approach, but I look forward to discussing in our stats meetings.

Thanks,
Karen

APAR0000005291

From: Michael Hughes [b6]
Date: Thursday, May 21, 2020 at 12:54 PM
To: "LaVange, Lisa M" [b6], "Proschan, Michael (NIH/NIAID) [E]" [b6], "Eron, Joseph J Jr" [b6], "Adam, Stacey (FNIH) [T]" [b6], "currier.judith" [b6], Eric Hughes [b6], Sandeep Menon [b6], "read.sarah" [b6], "Price, Dionne (FDA/CDER)" [b6], "Rubin, Daniel B. (FDA/CDER)" [b6], "Farley, John (FDA/CDER)" [b6], Karen Price [b6], "smith.davey" [b6], "chew.kara" [b6], "Wohl, David A" [b6], "Fischer, William A. II" [b6], "javan.arzhang" [b6], "Roa, Jhoanna" [b6], "kim.peter" [b6], "li.jonathan" [b6], "Marks, Gilbert (OS/ASPR/BARDA) (CTR)" [b6], "Kozak, Marina (OS/ASPR/BARDA)" [b6], "DeMarcus, Forrest" [b6], "Tountas, Karen (FNIH) [T]" [b6], "Wachtel, Jonathan" <jwachtel@deloitte.com>, Elizabeth Kim <elkim@deloitte.com>, "Parker, Ashley (NIH/OD) [E]" [b6], "roa.jhoanna" [b6], "Smith, David" [b6], Paul Klekotka [b6], Ajay Nirula [b6], "Elsaid, Olivia" <oelsaid@deloitte.com>, Robert Jan Benschop [b6], Lei Shen [b6]
Subject: [EXTERNAL] Re: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

EXTERNAL EMAIL: Use caution before replying, clicking links, and opening attachments.

Hi Lisa,

That's fine. Perhaps you and Karen could circulate some brief details of the Bayesian model framework and associated priors for each outcome measure you are envisaging? --- I think that would help in moving things along.

Looking forward to discussing,

Michael

From: LaVange, Lisa M [b6]

Sent: Thursday, May 21, 2020 1:34 PM

To: Michael Hughes; Proschan, Michael (NIH/NIAID) [E]; Eron, Joseph J Jr; Adam, Stacey (FNIH) [T]; currier.judith; Eric Hughes; Sandeep Menon; read.sarah; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; smith.davey; [b6] chew.kara; Wohl, David A; Fischer, William A. II; javan.arzhang; Roa, Jhoanna; [b6]; kim.peter; li.jonathan; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Kozak, Marina (OS/ASPR/BARDA)

Cc: DeMarcus, Forrest; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; roa.jhoanna; Smith, David; Paul Klekotka; Ajay Nirula; Elsaid, Olivia; Robert Jan Benschop; Lei Shen

Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Thanks, Michael. I believe it is premature to submit the protocol to your internal review committee. My take-away from yesterday's meeting was that the next step would be for the subgroup of statisticians to meet to discuss the simulations required for the revised trial design. The proposed revisions to the design are needed, in my opinion, to give us the type of flexible, fast-moving master protocol we need to screen a large amount of monoclonal antibodies. But we need to work out some of the design details, so let's have that next meeting as planned. Hoping we can schedule it for some time tomorrow and will work with Stacey to find a time.

Lisa

From: Michael Hughes [b6]

Sent: Thursday, May 21, 2020 11:03 AM

To: Proschan, Michael (NIH/NIAID) [E]; [b6]; LaVange, Lisa M [b6]; Eron, Joseph J Jr [b6]; Adam, Stacey (FNIH) [T]; [b6]; currier.judith [b6]; Eric Hughes [b6]; Sandeep Menon [b6]; read.sarah [b6]; Price, Dionne (FDA/CDER) [b6]; Rubin, Daniel B. (FDA/CDER) [b6]; Farley, John (FDA/CDER) [b6]; Karen Lynn Price [b6]; smith.davey [b6]; chew.kara [b6]; Wohl, David A [b6]; Fischer, William A. II [b6]; javan.arzhang [b6]; Roa, Jhoanna [b6]; kim.peter [b6]; li.jonathan [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]; Kozak, Marina (OS/ASPR/BARDA) [b6]

Cc: DeMarcus, Forrest [b6]; Tountas, Karen (FNIH) [T]; [b6]; Wachtel, Jonathan <jwachtel@deloitte.com>; Elizabeth Kim <elkim@deloitte.com>; Parker, Ashley (NIH/OD) [E]; [b6]; roa.jhoanna [b6]; Smith, David [b6]; Paul Klekotka [b6]; Ajay Nirula [b6]; Elsaid, Olivia <oelsaid@deloitte.com>; Robert Jan Benschop [b6]; Lei Shen [b6]

Subject: Re: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Hi All:

The ACTG team was hoping to submit the A5401 protocol tomorrow to the NIAID Clinical Science Review Committee for their review. The protocol design uses standard (widely-used) statistical methods for interim and final analyses but we received the feedback (attached) from ACTIV about moving to fully use Bayesian methods, so wanted to respond and get thoughts back as this is a substantial change --- and would mean that we would not be able to send for CSRC tomorrow.

I have particular concerns about the need to use the Bayesian paradigm, particularly for Phase III. For a given agent, the Phase 3 study is a fairly simple study involving evaluations for safety, clinical symptoms, and the primary outcome measure of hospitalization/death. We proposed to use standard group sequential monitoring methods which are flexible (using the Lan-DeMets approach for flexible timing of interim analyses with an O'Brien and Fleming type stopping guideline). I think the seamless phase II to phase 3 aspect of the design can be incorporated into this flexible approach by just considering the "look" at the data at the end of phase II as one "look" at the phase 3 primary outcome. This provides protection for the Type I error rate for each specific agent. We can overlay a the possibility of a simple futility rule, eg at $\geq 50\%$ enrollment, to allow stopping for lack of effect (can be justified using a Type II spending boundary, conditional power, or even a Bayesian type rule).

I think this is all quite straightforward. I worry that putting the Phase 3 trial into the Bayesian paradigm gains very little but adds complexity in terms of having to confirm that any Bayesian decision rule does protect Type I error rate for regulatory purposes, and in terms of explaining to many different companies and ultimately to a broad audience. In addition, if the study does go global, it increases the complexity of explaining to IRBs and other review groups.

I would prefer to leave Phase 3 using standard (widely used) statistical methods. I would also favor using standard methods for analysis of Phase 2 data but do agree that Bayesian analyses might also be used for the main efficacy outcome measures to provide an additional perspective in decision-making --- though the main graduation rules (eg observing an absolute 20% reduction in % positive for SARS-CoV-2 at a measurement time, and/or a 20% reduction in mean symptom duration) are straightforward and well-powered.

I would welcome feedback.

Many thanks,

Michael

From: Proschan, Michael (NIH/NIAID) [E] <[REDACTED]>
Sent: Thursday, May 21, 2020 8:52 AM
To: LaVange, Lisa M; Eron, Joseph J Jr; Adam, Stacey (FNIH) [T]; currier.judith; Eric Hughes; Sandeep Menon; read.sarah; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; smith.davey; Michael Hughes; [REDACTED]; chew.kara; Wohl, David A; Fischer, William A. II; javan.arzhang; Roa, Jhoanna; [REDACTED]; kim.peter; li.jonathan; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Kozak, Marina (OS/ASPR/BARDA)
Cc: DeMarcus, Forrest; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; roa.jhoanna; Smith, David; Paul Klekotka; Ajay Nirula; Elsaid, Olivia; Robert Jan Benshop; Lei Shen
Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

I think the question is whether we could stop early for efficacy as well as stopping early for futility. That could certainly be incorporated if you think there is a realistic possibility of crossing an efficacy boundary after only 50 people. At the halfway point, the O'Brien-Fleming-like spending function boundary for the z-score is close to 3, so you would have to see a very large z-score to stop that early for efficacy.

Mike.

From: LaVange, Lisa M <[REDACTED]>
Sent: Thursday, May 21, 2020 7:53 AM
To: Eron, Joseph J Jr <[REDACTED]>; Adam, Stacey (FNIH) [T] <[REDACTED]>; Judy Currier <[REDACTED]>; Eric Hughes <[REDACTED]>; Sandeep Menon <[REDACTED]>; Proschan, Michael (NIH/NIAID) [E] <[REDACTED]>; Read, Sarah (NIH/NIAID) [E] <[REDACTED]>; Price, Dionne (FDA/CDER) <[REDACTED]>; Rubin, Daniel B. (FDA/CDER) <[REDACTED]>; Farley, John (FDA/CDER) <[REDACTED]>; Karen Lynn Price <[REDACTED]>; Wohl, David A <[REDACTED]>; Fischer, William A. II <[REDACTED]>; Javan, Arzhang (NIH/NIAID) [E] <[REDACTED]>; Roa, Jhoanna <[REDACTED]>; Kim, Peter (NIH/NIAID) [E] <[REDACTED]>; Jonathan Li <[REDACTED]>; Marks, Gilbert (OS/ASPR/BARDA) (CTR) <[REDACTED]>; Kozak, Marina (OS/ASPR/BARDA) <[REDACTED]>
Cc: DeMarcus, Forrest <[REDACTED]>; Tountas, Karen (FNIH) [T] <[REDACTED]>; Wachtel, Jonathan <jwachtel@deloitte.com>; Elizabeth Kim <elkim@deloitte.com>; Parker, Ashley (NIH/OD) [E] <[REDACTED]>; Jhoanna Roa <[REDACTED]>; Smith, David <[REDACTED]>; Paul Klekotka <[REDACTED]>; Ajay Nirula <[REDACTED]>; Elsaid, Olivia <oelsaid@deloitte.com>; Robert Jan Benshop <[REDACTED]>; Lei Shen <[REDACTED]>
Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

This seems reasonable to me. We can define any basis that we think will be important for dropping dose arms or entire agents, having little to go on at this point in terms of what best predicts hospitalizations.

Lisa

From: Eron, Joseph J Jr

Sent: Wednesday, May 20, 2020 6:23 PM

To: Adam, Stacey (FNIH) [T] [b6]; Judy Currier [b6]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Sandeep Menon [b6]; Proschan, Michael (NIH/NIAID) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Price, Dionne (FDA/CDER) [b6]; Rubin, Daniel B. (FDA/CDER) [b6]; Farley, John (FDA/CDER) [b6]; Karen Lynn Price [b6]; Wohl, David A [b6]; Fischer, William A. II [b6]; Javan, Arzhang (NIH/NIAID) [E] [b6]; Roa, Jhoanna [b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Jonathan Li [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]; Kozak, Marina (OS/ASPR/BARDA) [b6];
Cc: DeMarcus, Forrest [b6]; Tountas, Karen (FNIH) [T] [b6]; Wachtel, Jonathan <jwachtel@deloitte.com>; Elizabeth Kim <elkim@deloitte.com>; Parker, Ashley (NIH/OD) [E] [b6]; Jhoanna Roa [b6]; Smith, David [b6]; Paul Klekotka [b6]; Ajay Nirula [b6]; Elsaid, Olivia <oelsaid@deloitte.com>; Robert Jan Benschop [b6]; Lei Shen [b6];
Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Here is my question for the group – especially Michael, John and Lisa

My question is whether there could be an interim “activity” analysis similar to the futility analysis listed below – the reason I ask is we have very little longitudinal data on the quantitative viral shedding and it is possible that this endpoint would have substantial power such that 50 patients per arm could provide an antiviral answer.

- If the Phase 2 portion of the Clinical mAb protocol is used for dose finding, this may be challenging with respect to size of the trial (number of treatment arms needed and available sample size per treatment arm). In addition, it may be appropriate to establish an interim futility analysis based on change in quantitative viral shedding to allow for discontinuation of a dose after e.g. 50 rather than 110 patients, or to allow early discontinuation of high doses due to safety findings.

Joe Eron MD

Professor of Medicine

University of North Carolina at Chapel Hill

School of Medicine

b6

From: Adam, Stacey (FNIH) [T] <[b6]>

Sent: Wednesday, May 20, 2020 5:42 PM

To: Judy Currier <[b6]>; Eric Hughes <[b6]>; LaVange, Lisa M <[b6]>; Sandeep Menon <[b6]>; Proschan, Michael (NIH/NIAID) [E] <[b6]>; Read, Sarah (NIH/NIAID) [E] <[b6]>; Price, Dionne (FDA/CDER) <[b6]>; Rubin, Daniel B. (FDA/CDER) <[b6]>; Farley, John (FDA/CDER) <[b6]>; Karen Lynn Price <[b6]>

Wohl, David A <[b6]>; Fischer, William A. II <[b6]>; Eron, Joseph J Jr <[b6]>; Javan, Arzhang (NIH/NIAID) [E] <[b6]>; Roa, Jhoanna <[b6]>; Kim, Peter (NIH/NIAID) [E] <[b6]>; Jonathan Li <[b6]>; Marks, Gilbert (OS/ASPR/BARDA) (CTR) <[b6]>; Kozak, Marina (OS/ASPR/BARDA) <[b6]>

Cc: DeMarcus, Forrest <[b6]>; Tountas, Karen (FNIH) [T] <[b6]>; Wachtel, Jonathan <jwachtel@deloitte.com>; Elizabeth Kim <elkim@deloitte.com>; Parker, Ashley (NIH/OD) [E] <[b6]>; Jhoanna Roa <[b6]>; Eron, Joseph J Jr <[b6]>; Smith, David <[b6]>; Paul Klekotka <[b6]>; Ajay Nirula <[b6]>; Elsaid, Olivia <oesaid@deloitte.com>; Robert Jan Benschop <[b6]>; Lei Shen <[b6]>

Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Dear mAb Outpatient WT,

The FDA team that has been working with ACTIV and sitting in on our writing team meetings for this protocol would like to offer the attached thoughts for the group's consideration on tonight's call.

Also, attaching again the updated synopsis that was discussed with the mAb Steering Committee earlier today.

Thanks,

Stacey

APAR0000005291

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

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From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 5/22/2020 11:46:22 AM
To: [b6]
[b6] Baric, Ralph
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
[b6] Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
[b6] Parker, Ashley (NIH/OD) [E]
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[b6] Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas /US
[b6] Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Tomas Cihlar
[b6]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]
CC: Diamond, Michael [b6] Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy
[b6]; Hughes, Eric [eric.hughes@novartis.com]; Jansen, Kathrin
[b6]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4b79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Kim, Elizabeth [elkim@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Wachtel, Jonathan [jwachtel@deloitte.com]; Prabhavathi Fernandes [b6]; Rose Li
[b6]; Dana Carluccio [b6] Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi

(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D
[b6]; Dave Frankowski [b6] Lowy, Douglas (NIH/NCI) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Louise Pitt
[b6] [b6] [b6] (USA)
[b6]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Gadbois, Ellen
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadbois]; Hild, Sheri (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
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Subject: RE: ACTIV Preclinical working group (Friday meeting)

Attachments: PRECLINICAL_Working Group_Agenda_20200522_d1.pptx; Animal Model Summaries.zip

Hi all,

Please find attached some materials to aid in our discussion today.

- * The first attachment contains the agenda as well as our WG's objectives and timeline.
- * The second attachment is a folder with the Animal Model 'one-pager' summaries.

Please let us know if you have any questions. Look forward to our discussion tomorrow.

Best,
Joe and Rosa

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T]

Sent: Tuesday, April 14, 2020 6:48 PM

To: [b6] Menetski, Joseph (FNIH) [T]; [b6]

[b6]

[b6]

[b6]

Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; [b6] Adams, Peter
(OS/ASPR/BARDA); Rao, Srinivas /US; Anderson, James (NIH/OD) [E]; Tomas Cihlar; Qashu, Felicia (NIH/OD) [E]
Cc: Diamond, Michael; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T];
Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E];
Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey
(FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan;
Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E];
Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Lowy,
Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; [b6]

[b6]

(USA); Nancy Haigwood; Gadbois, Ellen (NIH/OD) [E]; Hild, Sheri (NIH/OD) [E]

Subject: ACTIV Preclinical working group (Friday meeting)

When: Friday, May 22, 2020 11:00 AM-12:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: [b6]

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/22/2020 3:13:20 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Colli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [b6]; Keith Gottesdiener [b6]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Elliott Levy [b6]; Sandeep Menon [b6]; Amanda Peppercorn [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [b6]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [b6]; Wung, Peter /US [b6]; Karen Lynn Price [b6]; Pamela Tenaerts, M.D. [b6]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Burgess, Timothy [b6]; Beumont-Mauviel, Maria [JRDUS] [b6]; Peeters, Monika [JRDBE] [b6]; Woodfall, Brian [JRDUS] [b6]; Van Heeswijk, Rolf [JRDBE] [b6]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Bharucha_David [b6]; Gavin, Brian [b6]; Sadeh, Jonathan [b6]; Harler, Mary Beth [b6]; Mary Biggs [b6]; Demarcus [b6]; Macone, Erin [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [b6]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Melsheimer, Rich [CNTNL] [b6]
CC:
Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #20
Attachments: ACTIV_Therapeutics Clinical Master Protocol Sub Group_22May2020 Meeting Guide.pdf
Location: [b6]

Start: 5/22/2020 6:00:00 PM
End: 5/22/2020 6:30:00 PM
Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Patterson, Amy (NIH/NHLBI) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Burgess, Timothy; Beumont-Mauviel, Maria [JRDUS]; Peeters, Monika [JRDBE]; Woodfall, Brian [JRDUS]; Van Heeswijk, Rolf [JRDBE]; Brown, Jeremy (NIH/NINDS) [E]; Bharucha_David; Gavin, Brian; Sadeh, Jonathan; Harler, Mary Beth

Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Melsheimer, Rich [CNTNL]

Dear ACTIV TX-Clinical Master Protocol Subgroup,

For this meeting today, we have decide to split this meeting into two meetings to make most efficient use of everyone's time. This first 30 minute meeting will be the entire group with the companies for ACTIV-1 to discuss the next steps for this protocol. The second 30 minutes will now become a meeting of the mAb Steering Committee to finalize some decisions for the ACTIV-2 protocol that need to be completed by EOD today.

Thanks for your understanding.

Please find attached the slides for this first meeting today.

Thanks, Stacey

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Sent: 5/22/2020 3:17:22 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Karen Lynn Price [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Carlos O Garner [b6]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]
CC: Demarcus [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: ACTIV mAb Steering Committee Meeting
Location: [b6]
Start: 5/22/2020 6:30:00 PM
End: 5/22/2020 7:00:00 PM
Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Judy Currier; Eric Hughes; Lisa LaVange; Read, Sarah (NIH/NIAID) [E]; Karen Lynn Price; Higgs, Elizabeth (NIH/NIAID) [E]; Woodcock, Janet (FDA/CDER); Stein, Peter (FDA/CDER); Carlos O Garner; Bugin, Kevin; Marks, Gilbert (OS/ASPR/BARDA) (CTR)
Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]

Dear ACTIV TX-Clinical mAb Steering Committee,

This meeting will serve to finalize our decision for the inpatient mAb network and discuss any final outstanding questions for the ACTIV-2 outpatient protocol.

We could not get full quorum for the 1pm meeting, so we thought we would shoot for this time which many of you already had blocked on your calendars. Apologies to the few folks who might not be able to attend.

Thanks,

Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/22/2020 3:17:26 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E]; [b6] Butterton, Joan [b6]; Judy Currier [b6]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Read, Sarah (NIH/NIAID) [E]; [b6]; Karen Lynn Price [b6]; Higgs, Elizabeth (NIH/NIAID) [E]; [b6]; Woodcock, Janet (FDA/CDER) [b6]; Stein, Peter (FDA/CDER) [b6]; Carlos O Garner [b6]; Bugin, Kevin (FDA/CDER) [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]; Farley, John (FDA/CDER) [b6]
CC: Demarcus [b6]; Tountas, Karen (FNIH) [T] [b6]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]

Subject: ACTIV mAb Steering Committee Meeting

Location: [b6]

Start: 5/22/2020 6:30:00 PM

End: 5/22/2020 7:00:00 PM

Show Time As: Busy

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Judy Currier; Eric Hughes; Lisa LaVange; Read, Sarah (NIH/NIAID) [E]; Karen Lynn Price; Higgs, Elizabeth (NIH/NIAID) [E]; Woodcock, Janet (FDA/CDER); Stein, Peter (FDA/CDER); Carlos O Garner; Bugin, Kevin (FDA/CDER); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Farley, John (FDA/CDER)
Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]

Dear ACTIV TX-Clinical mAb Steering Committee,

This meeting will serve to finalize our decision for the inpatient mAb network and discuss any final outstanding questions for the ACTIV-2 outpatient protocol.

We could not get full quorum for the 1pm meeting, so we thought we would shoot for this time which many of you already had blocked on your calendars. Apologies to the few folks who might not be able to attend.

Thanks,

Stacey

Join Zoom Meeting

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Meeting ID: [b6]

Password: [b6]

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- US (New York)
- US (Germantown)
- US (San Jose)
- US (Tacoma)
- US (Houston)
- US (San Jose)

Meeting ID: **b6**

Password: **b6**

Find your local number: **b6**

From: Tountas, Karen (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
Sent: 5/22/2020 5:59:47 PM
To: Bascles, Lionel [b6]; Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [b6]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers, Betsy [b6]; Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshov, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshovj]; Garner, Carlos [b6]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Mensah, George (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura [b6]; Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Vincent, Mike [b6]; Weinmann, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang]
CC: Wachtel, Jonathan [jwachtel@deloitte.com]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [b6]; Jansen, Kathrin [b6]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [b6]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [marganderson@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Carluccio, Dana [b6]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny [b6]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [b6]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveson, Nancy [b6]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Criffield, Robin [b6]; Hamilton, Nancy [b6]; Hill, Zoe (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]; Minnich, Beth [b6]; Mueller-Reichenstein, Petra [b6]; Pico, Dianna (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=471cb6a63c8846a69073e1e968f3964c-picodf]; Quadros, Nora

b6; Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]

Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting

Location: **b6**

Start: 6/2/2020 1:00:00 PM

End: 6/2/2020 2:00:00 PM

Show Time As: Tentative

Recurrence: Weekly
every Tuesday from 9:00 AM to 10:00 AM

Required Attendees: Bascles, Lionel; Cohen, Myron; Corey, Larry; Davey, Victoria; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshov, James (NIH/NCI) [E]; Garner, Carlos; Goff, David (NIH/NHLBI) [E]; Kurilla, Mike; Mensah, George; Nayak, Seema (NIH/NIAID) [E]; Payton, Manzine; Resnansky, Laura; Sizemore, Christine (NIH/FIC) [E]; Srinivasan, Badhri; Stein, Peter (FDA/CDER); Vincent, Mike; Weinmann, Gail

Optional Attendees: Wachtel, Jonathan; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Ashley (NIH/OD) Parker [E] **b6**; Carluccio, Dana; Cheryl (FNIH) Melencio [T] **b6**; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Qashu, Felicia; Santos, Michael (FNIH); Tuvevson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Hill, Zoe (NIH/NHLBI) [C]; Minnich, Beth; Mueller-Reichenstein, Petra; Pico, Dianna; Quadros, Nora; Rebecca (NIH/NCATS) Katz [E] **b6**; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]

CT Capacity working group members, Many thanks for all the hard work that you have put into meeting our ACTIV mandate – looking forward to operationalizing the outcomes of your efforts. Let’s continue to meet regularly through the month of June (once a week) to continue to build out the inventories of CROs/SMOs/Networks/Sites and innovation/efficiencies, where needed, and, to integrate with other ACTIV working groups in support of protocol implementation (treatment and prevention). Best regards, Karen

Karen Tountas is inviting you to a scheduled Zoom meeting.

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US (Houston)

Meeting ID: **b6**

Password: **b6**

Find your local number: **b6**

From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40c04fef6f1e46f5b750753cd5a14f93-TOUNTASKH]
Sent: 5/22/2020 5:59:49 PM
To: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Bascles, Lionel
[b6] Cohen, Myron [b6] Corey, Larry [b6]
Victoria Davey [b6] Desrosiers, Betsy [b6]; Dickens, Jim
(NIH/NCATS) [C]; [b6] Doroshow, James (NIH/NCI) [E]; [b6] Garner, Carlos
[b6] Goff, David (NIH/NHLBI) [E]; [b6]; Kurilla, Michael (NIH/NCATS) [E]
[b6]; Mensah, George (NIH/NHLBI) [E]; [b6] Nayak, Seema (NIH/NIAID) [E]
[b6] Payton, Manizhe (NIH/NIAID) [E]; [b6] Resnansky, Laura
[b6] Sizemore, Christine (NIH/FIC) [E]; [b6] Srinivasan, Badhri
[b6]; Stein, Peter (FDA/CDER) [b6]; Vincent, Mike
[b6] Weinmann, Gail (NIH/NHLBI) [E]; [b6] Kublin MD, MPH, James
[b6] Ferguson, Sue [b6]
CC: Wachtel, Jonathan [jwachtel@deloitte.com]; Colvis, Christine (NIH/NCATS) [E]; [b6]; Hughes,
Eric [b6]; Jansen, Kathrin [b6]; Lowy, Douglas (NCI) [b6];
Read, Sarah (NIH/NIAID) [E]; [b6]; Young, John [b6]; Adam, Stacey (FNIH)
[T] [b6]; Anderson, Margaret [marganderson@deloitte.com]; Parker, Ashley (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Carluccio, Dana
[b6]; Melencio, Cheryl (FNIH) [T] [b6]; Gonzalez, Nina
[ningonzalez@deloitte.com]; Heaton, Penny [b6]; James, Stephanie (FNIH) [T]
[b6]; Li, Rose [b6]; Menetski, Joseph (FNIH) [T] [b6];
Qashu, Felicia (NIH/OD) [E]; [b6]; Santos, Michael (FNIH) [T] [b6]; Tuveson, Nancy
[b6]; Wholley, David (FNIH) [T] [b6]; Criffield, Robin
[b6]; Hamilton, Nancy [b6]; Hill, Zoe (NIH/NHLBI) [C]
[b6]; Minnich, Beth [b6]; Mueller-Reichenstein, Petra [petra.mueller-
[b6] Pico, Dianna (NIH/NHLBI) [C]; [b6]; Quadros, Nora
[b6]; Katz, Rebecca (NIH/NCATS) [E]; [b6]; Culp, Michelle (NIH/OD) [E]
[b6] Gadbois, Ellen (NIH/OD) [E]; [b6]; Kenny, Dermot
[b6]
Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting
Attachments: Untitled Attachment; Untitled Attachment; Canceled: ACTIV Clinical Trial Capacity Working Group - reporting meeting; Untitled Attachment; Untitled Attachment
Location: [b6]
Start: 6/2/2020 1:00:00 PM
End: 6/2/2020 2:00:00 PM
Show Time As: Busy
Recurrence: Weekly
every Tuesday from 9:00 AM to 10:00 AM
Required Attendees: Tountas, Karen (FNIH) [T]; Bascles, Lionel; Cohen, Myron; Corey, Larry; Davey, Victoria; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshow, James (NIH/NCI) [E]; Garner, Carlos; Goff, David (NIH/NHLBI) [E]; Kurilla, Mike; Mensah, George; Nayak, Seema (NIH/NIAID) [E]; Payton, Manzine; Resnansky, Laura; Sizemore, Christine (NIH/FIC) [E]; Srinivasan, Badhri; Stein, Peter (FDA/CDER); Vincent, Mike; Weinmann, Gail; Kublin MD, MPH, James; Ferguson, Sue
Optional Attendees: Wachtel, Jonathan; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Ashley (NIH/OD) Parker [E]
[b6] Carluccio, Dana; Cheryl (FNIH) Melencio [T] [b6]; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Qashu, Felicia; Santos, Michael (FNIH); Tuveson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Hill, Zoe (NIH/NHLBI) [C]; Minnich, Beth; Mueller-Reichenstein, Petra; Pico, Dianna; Quadros, Nora; Rebecca (NIH/NCATS) Katz [E]; [b6]; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Kenny, Dermot; [b6]

CT Capacity working group members, Many thanks for all the hard work that you have put into meeting our ACTIV mandate – looking forward to operationalizing the outcomes of your efforts. Let’s continue to meet regularly through the month of June (once a week) to continue to build out the inventories of CROs/SMOs/Networks/Sites and innovation/efficiencies, where needed, and, to integrate with other ACTIV working groups in support of protocol implementation (treatment and prevention). Best regards, Karen

Karen Tountas is inviting you to a scheduled Zoom meeting.

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From: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
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CC: Wachtel, Jonathan [jwachtel@deloitte.com]; Colvis, Christine (NIH/NCATS) [E] [b6]; Hughes, Eric [b6]; Jansen, Kathrin [b6]; Lowy, Douglas (NCI) [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Young, John [b6]; Adam, Stacey (FNIH) [T] [b6]; Anderson, Margaret [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Carluccio, Dana [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Gonzalez, Nina [ningonzalez@deloitte.com]; Heaton, Penny [b6]; James, Stephanie (FNIH) [T] [b6]; Li, Rose [b6]; Menetski, Joseph (FNIH) [T] [b6]; Qashu, Felicia (NIH/OD) [E] [b6]; Santos, Michael (FNIH) [T] [b6]; Tuveson, Nancy [b6]; Wholley, David (FNIH) [T] [b6]; Criffield, Robin [b6]; Hamilton, Nancy [b6]; Hill, Zoe (NIH/NHLBI) [C] [b6]; Minnich, Beth [b6]; Mueller-Reichenstein, Petra [b6]; Pico, Dianna (NIH/NHLBI) [C] [b6]; Quadros, Nora [b6]; Katz, Rebecca (NIH/NCATS) [E] [b6]; Culp, Michelle (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Kenny, Dermot [b6]
Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting
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Optional Attendees: Wachtel, Jonathan; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Ashley (NIH/OD) Parker [E] [b6]; Carluccio, Dana; Cheryl (FNIH) Melencio [T] [b6]; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Qashu, Felicia; Santos, Michael (FNIH); Tuveson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Hill, Zoe (NIH/NHLBI) [C]; Minnich, Beth; Mueller-Reichenstein, Petra; Pico, Dianna; Quadros, Nora; Rebecca (NIH/NCATS) Katz [E] [b6]; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Kenny, Dermot; [b6]

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Join Zoom Meeting

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US (Chicago)

US (San Jose)

US (San Jose)

US (Tacoma)

US (Houston)

Meeting ID: **b6**

Password: **b6**

Find your local number: **b6**

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/22/2020 6:35:02 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Judy Carrier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Karen Lynn Price [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Carlos O Garner [b6]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]
CC: Demarcus [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]

Subject: ACTIV mAb Steering Committee Meeting

Location: [b6]

Start: 5/22/2020 6:30:00 PM

End: 5/22/2020 7:00:00 PM

Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Judy Carrier; Eric Hughes; Lisa LaVange; Read, Sarah (NIH/NIAID) [E]; Karen Lynn Price; Higgs, Elizabeth (NIH/NIAID) [E]; Woodcock, Janet (FDA/CDER); Stein, Peter (FDA/CDER); Carlos O Garner; Bugin, Kevin (FDA/CDER); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Farley, John (FDA/CDER)
Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]

Dear ACTIV TX-Clinical mAb Steering Committee,

This meeting will serve to finalize our decision for the inpatient mAb network and discuss any final outstanding questions for the ACTIV-2 outpatient protocol.

We could not get full quorum for the 1pm meeting, so we thought we would shoot for this time which many of you already had blocked on your calendars. Apologies to the few folks who might not be able to attend.

Thanks,

Stacey

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 5/22/2020 8:13:29 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Dolsten, Mikael [b6]; Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda]; Pao, William [b6]; Plump, Andrew [b6]; Stoffels, Paul [b6]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [b6]; Hughes, Eric [b6]; Jansen, Kathrin [b6]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [b6]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd42247548e596778304f781f-austinc]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa [rosalvarez@deloitte.com]; Anderson, Margaret [marganderson@deloitte.com]; Chen, Helen [qingchen@deloitte.com]; Elsaid, Olivia [oelsaid@deloitte.com]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Kim, Elizabeth [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Stratton, Ben [bstratton@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Barasch, Kimberly (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Conrad, Patricia (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Perala, Mie [b6]; Protasiewicz, Ann [b6]; Riccobene, Kim [b6]; Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Togashi, Mieko (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togashim]; Zottoli, Jessica [b6]

Subject: ACTIV Executive Committee Teleconference

Location: [b6]

Start: 6/17/2020 4:00:00 PM

End: 6/17/2020 5:30:00 PM

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Required Attendees: Collins, Francis (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Fauci, Anthony (NIH/NIAID) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Marks, Peter (FDA/CBER); Pao, William; Plump, Andrew; Stoffels, Paul; Woodcock, Janet (FDA/CDER); Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Anderson, James (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]; Burklow, John (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Freire, Maria (FNIH) [T]; Gadbois, Ellen (NIH/OD) [E]; Hallett, Adrienne (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Myles, Renate (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]

Optional Attendees: Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Kim, Elizabeth; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Zottoli, Jessica

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Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Peralá, Mie; Protasiewicz, Ann; Riccobene, Kim; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Zottoli, Jessica; Lowy, Douglas (NIH/NCI) [E]; Lucas Smalldon

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Sent: 5/22/2020 8:13:31 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [b6]; Disbrow, Gary (OS/ASPR/BARDA) [b6]; Dolsten, Mikael [b6]; Fauci, Anthony (NIH/NIAID) [E] [b6]; Gibbons, Gary (NIH/NHLBI) [E] [b6]; Marks, Peter (FDA/CBER) [b6]; Pao, William [b6]; Plump, Andrew [b6]; Stoffels, Paul [b6]; Woodcock, Janet (FDA/CDER) [b6]; Colvis, Christine (NIH/NCATS) [E] [b6]; Desrosiers, Betsy [b6]; Hughes, Eric [b6]; Jansen, Kathrin [b6]; Kurilla, Michael (NIH/NCATS) [E] [b6]; Lowy, Douglas (NCI) [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Young, John [b6]; Anderson, James (NIH/OD) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Burklow, John (NIH/OD) [E] [b6]; Culp, Michelle (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Hallett, Adrienne (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Myles, Renate (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabak]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
CC: Adam, Stacey (FNIH) [T] [b6]; Alvarez, Rosa [rosalvarez@deloitte.com]; Anderson, Margaret [marganderson@deloitte.com]; Chen, Helen [qingchen@deloitte.com]; Elsaid, Olivia [oelsaid@deloitte.com]; Gonzalez, Nina [ningonzalez@deloitte.com]; James, Stephanie (FNIH) [T] [b6]; Kim, Elizabeth [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]; Stratton, Ben [bstratton@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Tountas, Karen (FNIH) [T] [b6]; Wachtel, Jonathan [jwachtel@deloitte.com]; Wholley, David (FNIH) [T] [b6]; Barasch, Kimberly (NIH/NIAID) [C] [b6]; Conrad, Patricia (NIH/NIAID) [E] [b6]; Dimishkov, Roxanne (NIH/NHLBI) [C] [b6]; McManus, Ayanna (NIH/OD) [E] [b6]; Peralá, Mie [b6]; Protasiewicz, Ann [b6]; Riccobene, Kim [b6]; Thomas, Ashley (FDA/CDER) [b6]; Wood, Gretchen (NIH/OD) [E] [b6]; Togashi, Mieko (NIH/NCI) [E] [b6]; Zottoli, Jessica [b6]; Lowy, Douglas (NIH/NCI) [E] [b6]; Lucas Smalldon [b6]
Subject: ACTIV Executive Committee Teleconference
Location: [b6]
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Required Attendees: Collins, Francis (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Fauci, Anthony (NIH/NIAID) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Marks, Peter (FDA/CBER); Pao, William; Plump, Andrew; Stoffels, Paul; Woodcock, Janet (FDA/CDER); Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Anderson, James (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]; Burklow, John (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Freire, Maria (FNIH) [T]; Gadbois, Ellen (NIH/OD) [E]; Hallett, Adrienne (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Myles, Renate (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]
Optional Attendees: Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Kim, Elizabeth; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Peralá, Mie;

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
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To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Dolsten, Mikael [b6] Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda]; Pao, William [b6] Plump, Andrew [b6]; Stoffels, Paul [b6]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [b6] Hughes, Eric [b6]; Jansen, Kathrin [b6]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [b6]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd42247548e596778304f781f-austinc]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa [rosalvarez@deloitte.com]; Anderson, Margaret [marganderson@deloitte.com]; Chen, Helen [qingchen@deloitte.com]; Elsaid, Olivia [oelsaid@deloitte.com]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Kim, Elizabeth [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb683de44e18ef4cc6952f65f80-santosmr]; Stratton, Ben [bstratton@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Barasch, Kimberly (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Conrad, Patricia (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Perala, Mie [b6] Protasiewicz, Ann [b6]; Riccobene, Kim [b6] Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Togashi, Mieko (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togashim]; Zottoli, Jessica [b6]

Subject: ACTIV Executive Committee Teleconference

Location: [b6]

Start: 6/17/2020 4:00:00 PM

End: 6/17/2020 5:30:00 PM

Show Time As: Busy

Required Attendees: Collins, Francis (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Fauci, Anthony (NIH/NIAID) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Marks, Peter (FDA/CBER); Pao, William; Plump, Andrew; Stoffels, Paul; Woodcock, Janet (FDA/CDER); Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Anderson, James (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]; Burklow, John (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Freire, Maria (FNIH) [T]; Gadbois, Ellen (NIH/OD) [E]; Hallett, Adrienne (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Myles, Renate (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]

Optional Attendees: Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Kim, Elizabeth; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Zottoli, Jessica

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Meeting ID: **b6**

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/22/2020 9:53:16 PM
To: Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [b6] Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [b6]; Keith Gottesdiener [b6]; Elliott Levy [b6]; Wung, Peter /US [b6]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [b6]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bafd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Rose Li Central Account [FNIH@roseliassociates.com]
Subject: Summary of ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #12
Attachments: 2020-05-21_TX-Clinical_WG_Agent_Prioritization_Committee_Meeting-Summary.pdf

Dear ACTIV TX-Clinical Agent Prioritization Subgroup,

Please find attached the formal summary from our meeting yesterday. If you have any additions or amendments, please contact me.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health
Direct: [b6] Mobile: [b6]
fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/23/2020 1:23:29 AM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Coll]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [b6]; Keith Gottesdiener [b6]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Elliott Levy [b6]; Sandeep Menon [b6]; Amanda Peppercorn [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [b6]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [b6]; Wung, Peter /US [b6]; Karen Lynn Price [b6]; Pamela Tenaerts, M.D. [b6]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Burgess, Timothy [b6]; Beumont-Mauviel, Maria [JRDUS] [b6]; Peeters, Monika [JRDBE] [b6]; Woodfall, Brian [JRDUS] [b6]; Van Heeswijk, Rolf [JRDBE] [b6]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Bharucha_David [b6]; Gavin, Brian [b6]; Sadeh, Jonathan [b6]; Harler, Mary Beth [b6]; Mary Biggs [b6]; Demarcus [b6]; Macone, Erin [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [b6]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Melsheimer, Rich [CNTNL] [b6]
Subject: Follow-up to ACTIV TX-Clinical Master Protocol Subgroup Meeting #20
Attachments: ACTIV_Therapeutics-Clinical_Master Protocol Subgroup_22May2020_Meeting Notes.pdf

Dear ACTIV TX-Clinical Master Protocol Subgroup,

Please find the summary of today's call. If you have any additions or amendments, please feel free to send them to me.

As the action items articulate, I will be reaching out to the companies and a few MPSG members to arrange writing tea meetings next week. Please let me know if you would like to be on that team.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/23/2020 4:58:59 PM
To: Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Sandeep Menon [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f29042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price [b6]; Eron, Joe [b6]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; [b6] Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]
CC: Demarcus [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa [b6]; Eron, Joseph J Jr [b6]; Smith, David [b6]; Paul Klekotka [b6]; Ajay Nirula [b6]
Subject: ACTIV-2 Writing Team Meeting
Location: [b6]
Start: 5/26/2020 6:00:00 PM
End: 5/26/2020 7:00:00 PM
Show Time As: Tentative

Required Attendees: Judy Currier; Eric Hughes; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; [b6]; Eron, Joe; Javan, Arzhang (NIH/NIAID) [E]; Roa, Jhoanna; [b6] Kim, Peter (NIH/NIAID) [E]
Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Jhoanna Roa; Eron, Joseph J Jr; Smith, David; Paul Klekotka; Ajay Nirula

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/23/2020 4:59:02 PM
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CC: Demarcus [b6]; Tountas, Karen (FNIH) [T] [b6]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa [b6]; Eron, Joseph J Jr [b6]; Smith, David [b6]; Paul Klekotka [b6]; Ajay Nirula [b6]; Chen, Helen Q. [qingchen@deloitte.com]
Subject: ACTIV-2 Writing Team Meeting
Location: [b6]
Start: 5/26/2020 6:00:00 PM
End: 5/26/2020 7:00:00 PM
Show Time As: Busy

Required Attendees: Judy Currier; Eric Hughes; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; [b6]; Eron, Joe; Javan, Arzhang (NIH/NIAID) [E]; Roa, Jhoanna; [b6]; Kim, Peter (NIH/NIAID) [E]; Kozak, Marina (OS/ASPR/BARDA)
Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Jhoanna Roa; Eron, Joseph J Jr; Smith, David; Paul Klekotka; Ajay Nirula; Chen, Helen Q.

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/23/2020 5:01:44 PM
To: Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Sandeep Menon [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price [b6]; Eron, Joe [b6]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co] [b6]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Carlos O Garner [b6]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]
CC: Demarcus [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jhoanna Roa [b6]; Eron, Joseph J Jr [b6]; Smith, David [b6]; Paul Klekotka [b6]; Ajay Nirula [b6]; Lucas Smalldon [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [b6]; Chen, Helen Q. [qingchen@deloitte.com]
Subject: ACTIV-2 Writing Team and mAb Steering Committee Joint Meeting - Review Protocol
Location: [b6]
Start: 5/27/2020 5:00:00 PM
End: 5/27/2020 6:00:00 PM
Show Time As: Tentative

Required Attendees: Judy Currier; Eric Hughes; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; [b6]
[b6] Eron, Joe; Javan, Arzhang (NIH/NIAID) [E]; Roa, Jhoanna; [b6] Kim, Peter (NIH/NIAID) [E]; Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Higgs, Elizabeth (NIH/NIAID) [E]; Woodcock, Janet (FDA/CDER); Stein, Peter (FDA/CDER); Carlos O Garner; Bugin, Kevin; Marks, Gilbert (OS/ASPR/BARDA) (CTR)

Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Jhoanna Roa; Eron, Joseph J Jr; Smith, David; Paul Klekotka; Ajay Nirula; Lucas Smalldon; Rose Li Central Account; Dana Carluccio; Chen, Helen Q.

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Sent: 5/23/2020 5:01:46 PM
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Subject: ACTIV-2 Writing Team and mAb Steering Committee Joint Meeting - Protocol Update
Attachments: Adapt Out COVID CSRC 052520.pdf; a5401-d06-052520v2.docx; ACTIV_TX-Clinical_ACTIV-2 Writing Team & mAb SteerCo Joint Meeting Agenda_0527020.pdf; Capture Study eligible_Tx Clinical.PNG
Location: [b6]

Start: 5/27/2020 5:00:00 PM
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Dear ACTIV-2 Writing Team and ACTIV mAb Steering Committee,

We are looking forward to this joint meeting tomorrow in which the ACTIV-2 team will share their progress on the mAb outpatient master protocol with the Steering Committee. The team will review the current thinking within the protocol. Then they would like to solicit feedback from the Steering Committee about a few remaining questions that could still alter the protocol structure.

Please find attached the materials for tomorrow:

1. Meeting agenda
2. Current ACTIV-2 master protocol
3. Slides summarizing the current protocol

Please note that the stats team is still working to insert the final design of the Bayesian framework that will be used for agents beyond the first drug(s) into the trial for progression from Phase 2 to 3 within the study. This framework will not apply to the early entrants since prior learnings will be needed to inform the Bayesian model.

In addition, the team is waiting on some critical feedback from the FDA about how to address company feedback for a Phase 1(ish) safety/dose “run-in” study protocol that could be paired with the master protocol and potentially be overseen by ACTIV.

Thanks,
Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/23/2020 5:04:08 PM
To: Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Sandeep Menon [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price [b6]; [b6]; Eron, Joe [b6]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; [b6] Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]
CC: Demarcus [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa [b6]; Eron, Joseph J Jr [b6]; Smith, David [b6]; Paul Klekotka [b6]; Ajay Nirula [b6]
Subject: ACTIV-2 Writing Team Meeting
Location: [b6]
Start: 5/28/2020 3:00:00 PM
End: 5/28/2020 4:00:00 PM
Show Time As: Tentative

Required Attendees: Judy Currier; Eric Hughes; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; [b6]; Eron, Joe; Javan, Arzhang (NIH/NIAID) [E]; Roa, Jhoanna; [b6]; Kim, Peter (NIH/NIAID) [E]
Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Jhoanna Roa; Eron, Joseph J Jr; Smith, David; Paul Klekotka; Ajay Nirula

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/23/2020 5:04:09 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Judy Carrier [b6]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Sandeep Menon [b6]; Proschan, Michael (NIH/NIAID) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Price, Dionne (FDA/CDER) [b6]; Rubin, Daniel B. (FDA/CDER) [b6]; Farley, John (FDA/CDER) [b6]; Karen Lynn Price [b6]; Eron, Joe [b6]; Javan, Arzhang (NIH/NIAID) [E] [b6]; Roa, Jhoanna [b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Kozak, Marina (OS/ASPR/BARDA) [b6]
CC: Demarcus [b6]; Tountas, Karen (FNIH) [T] [b6]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa [b6]; Eron, Joseph J Jr [b6]; Smith, David [b6]; Paul Klekotka [b6]; Ajay Nirula [b6]; Chen, Helen Q. [qingchen@deloitte.com]
Subject: ACTIV-2 Writing Team Meeting
Attachments: ACTIV_TX-Clinical_ACTIV-2 Writing Team Meeting Agenda_05282020.pdf
Location: [b6]
Start: 5/28/2020 3:00:00 PM
End: 5/28/2020 4:00:00 PM
Show Time As: Busy

Required Attendees: Judy Carrier; Eric Hughes; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; [b6]
Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Jhoanna Roa; Eron, Joseph J Jr; Smith, David; Paul Klekotka; Ajay Nirula; Chen, Helen Q.

Dear ACTIV-2 Writing Team,

Please find attached the proposed agenda for tomorrow's meeting. We may also have some outcomes and slides to share from the stats meeting preceding this, but those will be distributed after that call.

Thanks,
Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/23/2020 5:17:00 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [b6]; LaVange, Lisa M [b6] Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Karen Lynn Price [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Carlos O Garner [b6]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]
CC: Demarcus [b6] Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Chen, Helen Q. [qingchen@deloitte.com]

Subject: ACTIV mAb Steering Committee Meeting

Location: [b6]

Start: 5/29/2020 6:00:00 PM

End: 5/29/2020 7:00:00 PM

Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Judy Currier; Eric Hughes; Lisa LaVange; Read, Sarah (NIH/NIAID) [E]; Karen Lynn Price; Higgs, Elizabeth (NIH/NIAID) [E]; Woodcock, Janet (FDA/CDER); Stein, Peter (FDA/CDER); Carlos O Garner; Bugin, Kevin; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Farley, John (FDA/CDER)
Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Chen, Helen Q.

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Meeting ID: **b6**

Password: **b6**

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/23/2020 5:17:02 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E]; [b6]; Butterson, Joan [b6]; Judy Currier [b6]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Read, Sarah (NIH/NIAID) [E]; [b6]; Karen Lynn Price [b6]; Higgs, Elizabeth (NIH/NIAID) [E]; [b6]; Woodcock, Janet (FDA/CDER); [b6]; Stein, Peter (FDA/CDER); [b6]; Carlos O Garner; [b6]; Bugin, Kevin (FDA/CDER) [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]; Farley, John (FDA/CDER); [b6]; Jens Lundgren [b6]
CC: Demarcus [b6]; Tountas, Karen (FNIH) [T]; [b6]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Chen, Helen Q. [qingchen@deloitte.com]; Salathin, Carla [b6]

Subject: ACTIV mAb Steering Committee Meeting
Attachments: ACTIV_TX-Clinical_mAb Steering Committee Meeting_20200529.pdf
Location: [b6]

Start: 5/29/2020 6:00:00 PM
End: 5/29/2020 7:00:00 PM
Show Time As: Busy

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Judy Currier; Eric Hughes; Lisa LaVange; Read, Sarah (NIH/NIAID) [E]; Karen Lynn Price; Higgs, Elizabeth (NIH/NIAID) [E]; Woodcock, Janet (FDA/CDER); Stein, Peter (FDA/CDER); Carlos O Garner; Bugin, Kevin; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Farley, John (FDA/CDER); Jens Lundgren
Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Chen, Helen Q.; Salathin, Carla

Dear mAb Steering Committee,

Please find attached the proposed agenda and slides for tomorrow. Please let us know if we need to add anything else to the agenda.

Thanks,
Stacey

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From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
Sent: 5/25/2020 7:43:44 PM
To: Vincent, Mike [b6]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Bascles, Lionel [b6]; Corey, Larry [lcorey@fredhutch.org]; Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers, Betsy [b6]; Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshov, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshovj]; Garner, Carlos [b6]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Resnansky, Laura [b6]; Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wachtel, Jonathan [jwachtel@deloitte.com]; Mensah, George (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Weinmann, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang]
CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Jintanat Ananworanich [b6]; Walker, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e577497e37b244168bd76c0b8827ca71-Robert.Walk]; Mason, Robin (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77156b112de94c439dbccb6894954618-Robin.Mason]; Hughes, Eric [b6]; Criffield, Robin [b6]; Hamilton, Nancy [b6]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Minnich, Beth [b6]; Mueller-Reichenstein, Petra [b6]; Quadros, Nora [b6]; Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Hill, Zoe (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [marganderson@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Carluccio, Dana [b6]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny [b6]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [b6]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuvevsson, Nancy
[b6]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Colvis, Christine
(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Jansen, Kathrin
[b6]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John
[b6]

Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting
Attachments: Clinical Trial Capacity Working Group Meeting Agenda_05262020.pdf
Location: [b6]

Start: 5/26/2020 1:00:00 PM
End: 5/26/2020 2:00:00 PM
Show Time As: Tentative

Recurrence: Weekly
every Tuesday and Friday from 9:00 AM to 10:00 AM
Required Attendees: Vincent, Mike; Goff, David (NIH/NHLBI) [E]; Bascles, Lionel; Corey, Larry; Cohen, Myron; Davey, Victoria; Desrosiers ,
Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshov, James (NIH/NCI) [E]; Garner, Carlos; Kurilla, Mike; Nayak, Seema
(NIH/NIAID) [E]; Payton, Manzine; Qashu, Felicia; Resnansky, Laura; Sizemore, Christine (NIH/FIC) [E]; Srinivasan,
Badhri; Stein, Peter (FDA/CDER); Wachtel, Jonathan; Mensah, George; Weinmann, Gail
Optional Attendees: Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Jintanat Ananworanich; Walker, Robert (OS/ASPR/BARDA);
Mason, Robin (OS/ASPR/BARDA); Hughes, Eric; Criffield, Robin; Hamilton, Nancy; Melencio, Cheryl (FNIH) [T];
Minnich, Beth; Mueller-Reichenstein, Petra; Quadros, Nora; Rebecca (NIH/NCATS) Katz [E] [b6]
Zoe (NIH/NHLBI) Hill [C] [b6]; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Ashley (NIH/OD) Parker [E]
[b6]; Carluccio, Dana; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski,
Joseph (FNIH) [T]; Santos, Michael (FNIH); Tuvevsson, Nancy; Wholley, David (FNIH) [T]; Colvis, Christine (NIH/NCATS)
[E]; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John

Dear Colleagues, Attached is the Agenda for the Clinical Trial Capacity Working Group agenda. I am please to let you know that BARDA (Biomedical Advanced Research and Development Authority, U.S. Dept of Health and Human Services) will join the meeting to talk about their CRO relationships. With best regards, Karen

Dear Clinical Trial Capacity WG members, This will extend our full working group calls through the end of May. We'll assess the need for further meetings at the end of the month. Many thanks for your participation! Karen

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Subject: Summary and action items - CT Capacity WG meeting #11

Attachments: Clinical_Trial_Capacity_Working_Group_Meeting_11_Final.pdf

Dear Clinical Trial Capacity Working Group Members,

Attached is the summary and action items for meeting #11 (May 22, 2020) of the full working group. The summary from the call today will be distributed as soon as it is available. The next full working group meeting is scheduled for Friday, May 29 at 9 am eastern time USA.

With best regards,
Karen

Karen H. Tountas, PhD

Scientific Program Manager

Foundation for the National Institutes of Health

[b6] | fnih.org

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CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bafd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Rose Li Central Account [FNIH@roseliassociates.com]; Chen, Helen Q. [qingchen@deloitte.com]
Subject: Inquiry about the ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #13

Dear ACTIV Agent Prioritization Subgroup,

It has become apparent that our mAb Prioritization Subteam will need to have a second meeting this week.

Since we are still working on getting back the data requested for this larger team, I was hoping this group would allow us to cancel this larger meeting and use the time to have just a meeting of our mAb Prioritization Subteam.

This group will get an overall update on the progress of the TX-Clinical WG at our large WG meeting with both the Agent Prioritization and Master Protocol teams, and we will work to get individual meetings for the other Agent Prioritization Subteams on the books for next week if the data has been fully assembled.

Please let me know if you have any opposition to canceling the meeting to allow for the smaller group meeting. If a majority would prefer to keep the meeting, we will find another time for the small group.

Thanks,
Stacey

APAR0000005284

Stacey J. Adam, PhD

Director, Cancer

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Subject: Materials for ACTIV-2 Writing Team and mAb Steering Committee Joint Meeting
Attachments: ACTIV_TX-Clinical_ACTIV-2 Writing Team & mAb SteerCo Joint Meeting Agenda_0527020.pdf; a5401-d06-052520v2.docx; Adapt Out COVID CSRC 052520.pdf

Dear ACTIV-2 Writing Team and ACTIV mAb Steering Committee,

APAR0000005280

We are looking forward to this joint meeting tomorrow in which the ACTIV-2 team will share their progress on the mAb outpatient master protocol with the Steering Committee. The team will review the current thinking within the protocol. Then they would like to solicit feedback from the Steering Committee about a few remaining questions that could still alter the protocol structure.

Please find attached the materials for tomorrow:

1. Meeting agenda
2. Current ACTIV-2 master protocol
3. Slides summarizing the current protocol

Please note that the stats team is still working to insert the final design of the Bayesian framework that will be used for agents beyond the first drug(s) into the trial for progression from Phase 2 to 3 within the study. This framework will not apply to the early entrants since prior learnings will be needed to inform the Bayesian model.

In addition, the team is waiting on some critical feedback from the FDA about how to address company feedback for a Phase 1(ish) safety/dose “run-in” study protocol that could be paired with the master protocol and potentially be overseen by ACTIV.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

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Subject: ACTIV-2 Writing Team and mAb Steering Committee Joint Meeting - Protocol Update
Attachments: Adapt Out COVID CSRC 052520.pdf; a5401-d06-052520v2.docx; ACTIV_TX-Clinical_ACTIV-2 Writing Team & mAb SteerCo Joint Meeting Agenda_0527020.pdf
Location: [b6]
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End: 5/27/2020 6:00:00 PM

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Required Attendees: Judy Currier; Eric Hughes; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; [b6]
[b6]; Eron, Joe; Javan, Arzhang (NIH/NIAID) [E]; Roa, Jhoanna; [b6]; Kim, Peter (NIH/NIAID) [E]; Bozzette, Sam (NIH/NCATS) [E]; Joan Butters; Higgs, Elizabeth (NIH/NIAID) [E]; Woodcock, Janet (FDA/CDER); Stein, Peter (FDA/CDER); Carlos O Garner; Bugin, Kevin; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Kozak, Marina (OS/ASPR/BARDA)
Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Jhoanna Roa; Eron, Joseph J Jr; Smith, David; Paul Klekotka; Ajay Nirula; Lucas Smalldon; Rose Li Central Account; Dana Carluccio; Chen, Helen Q.

Dear ACTIV-2 Writing Team and ACTIV mAb Steering Committee,

We are looking forward to this joint meeting tomorrow in which the ACTIV-2 team will share their progress on the mAb outpatient master protocol with the Steering Committee. The team will review the current thinking within the protocol. Then they would like to solicit feedback from the Steering Committee about a few remaining questions that could still alter the protocol structure.

Please find attached the materials for tomorrow:

1. Meeting agenda
2. Current ACTIV-2 master protocol
3. Slides summarizing the current protocol

Please note that the stats team is still working to insert the final design of the Bayesian framework that will be used for agents beyond the first drug(s) into the trial for progression from Phase 2 to 3 within the study. This framework will not apply to the early entrants since prior learnings will be needed to inform the Bayesian model.

In addition, the team is waiting on some critical feedback from the FDA about how to address company feedback for a Phase 1(ish) safety/dose "run-in" study protocol that could be paired with the master protocol and potentially be overseen by ACTIV.

Thanks,
Stacey

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Sent: 5/27/2020 1:20:05 AM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [b6]; Eisner, Mark [b6]; Gottesdiener, Keith [b6]; Hughes, Eric [b6]; Judy Carrier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; LaVange, Lisa [b6]; Levy, Elliot [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [b6]; Patel, Naimish [b6]; Peppercorn, Amanda [b6]; Poole, Mike [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Amanda Peppercorn [b6]; Garner, Carl [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Burgess, Timothy [b6]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-roosenbey]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]
CC: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [b6]; Jansen, Kathrin [b6]; Kim, Elizabeth [elkim@deloitte.com]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Wachtel, Jonathan [jwachtel@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Tolman, Brett [btolman@deloitte.com]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Chen, Helen Q. [qingchen@deloitte.com]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]

Subject: COVID-19 Status Reports and Dashboards from VA and UC System

Attachments: Copy of DailyReport_20200522.xlsx; UC Report 5-22-20.pdf

Dear ACTIV TX-Clinical Working Group,

Please find attached some initial RWD that the FDA team has been kind enough to give us access to and will update for our group each week if we would find it useful.

Please let me know if either our Agent Prioritization Subgroup or the Master Protocol Subgroup would find this data useful as we are prioritizing agents and planning trials. If so, I will work with Peter Stein to ensure our group gets the updated information at the proper cadence.

Please do not share beyond the ACTIV group at this time.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Stein, Peter [b6]

Sent: Monday, May 25, 2020 6:59 PM

To: Adam, Stacey (FNIH) [T] [b6]

Subject: reports

Stacey,

Amy Abernathy is coordinating a group pulling in RWD from a number of sources – with daily reports from the VA and UC system. She has permission to have these shared with the ACTIV group – so I’ve attached reports from last week, and if useful, we can have these at whatever frequency we prefer.

Regards, Peter

Peter P. Stein, MD
Director, Office of New Drugs, CDER/FDA

GADB0000003764

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
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To: Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Sandeep Menon [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f29042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price [b6]; Eron, Joe [b6]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co] [b6]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]
CC: Demarcus [b6] Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa [b6]; Eron, Joseph J Jr [b6]; Smith, David [b6]; Paul Klekotka [b6]; Ajay Nirula [b6]; Chen, Helen Q. [qingchen@deloitte.com]
Subject: Follow-up to ACTIV-2 Writing Team Meeting
Attachments: ACTIV_Therapeutics-Clinical_Master Protocol Subgroup_ACTIV-2 Writing Team Meeting Minutes_20200526.pdf

Dear ACTIV-2 Writing Team,

Please find attached the notes from today's meeting.

As a brief update, the questions have been email to Peter Stein and John Farley from the FDA, and we will keep the group posted on what we hear.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
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11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



APAR0000005274

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
Sent: 5/27/2020 3:42:28 AM
To: [b6]
Gruber, Marion (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ebf7a8eb8dd541b2883a966ea5afd809-GRUBER.fda]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; [b6]
[b6] Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001a98d300d14b20b18c01181eb843e0-Arvinam.Sta]; [b6]
[b6] (USA) [b6]; Bett, Andrew J [b6];
Gilbert PhD, Peter B [b6]; Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33958e1252cf4266bffc8d94988f5715-kneuzil.com]; [b6]
[b6] (USA) [b6]; Thornburg, Natalie (CDC/DDID/NCIRD/DVD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c8d079e00a5649639c6f1425f3bb075f-nax3]; Greg Glenn [b6]
Cavaleri Marco [b6]
CC: [b6] Jeneffer Haynes [b6]
Tolman, Brett [btolman@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Brian Rosen [b6]
Cheryl Keech [ckeech@Novavax.com]
Subject: Agenda for the Protective Immune Responses Sub-Group meeting
Attachments: M_Cavaleri_regulatory_framework_emergencies.ppt

Dear Protective Immune Responses Sub-Group members,

We're looking forward to today's (Wednesday) meeting, at 9am ET (6am PT / 3pm CEST).

Since our last meeting, Marco kindly shared the attached document on EMA and member state regulatory pathways for vaccine use and approval. Unfortunately Marco won't be able to join this meeting, but has offered to discuss the EMA pathways at a future meeting.

Our recent meetings have focused primarily on understanding regulatory pathways for vaccine use and approval, and the types of evidence that factor into regulatory decisions for different pathways, with two presentations on upcoming sources of evidence (NIAID NHP challenge studies using sera/IgG/mAbs and CDC immunological studies). A key goal of this group is to facilitate vaccine developers to generate evidence that can support evaluation of vaccine efficacy. For today's meeting, we plan to discuss the different categories of evidence and identify priorities for ACTIV to engage to be supportive.

We look forward to the discussion. If you are unable to attend please feel free to send comments or questions before or after the meeting.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

APAR0000006190

From: Santos, Michael (FNIH) [T]
Sent: Tuesday, May 26, 2020 12:19 AM
Subject: Notes from the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Please find attached notes and materials from our meeting last week. Thanks again to Donna and Natalie for presenting, and as always to Marion for her contributions to the regulatory pathways during the meeting and subsequently.

We will be in touch again soon regarding this week's meeting. Feel free to reach out any time with questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Tuesday, May 19, 2020 8:56 AM
Subject: Agenda and Materials for today's Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Please find attached two documents for today's Protective Immune Responses Sub-Group meeting (2pm ET / 11am PT / 8pm CEST):

- An updated table of pathways to vaccine use
- Notes from the last Sub-Group meeting (with my apologies for the delay)

For today's meeting, the agenda items are:

- Discussion of the updated pathways table and next steps
- An overview of the CDC's serology activities by Natalie

We're looking forward to the discussion today. As always, if you are unable to attend please feel free to send comments or questions before or after the meeting.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science
Foundation for the National Institutes of Health
b6 fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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From: Alvarez, Rosa Maria [rosalvarez@deloitte.com]
Sent: 5/27/2020 12:16:42 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetski] [b6]
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[b6]; Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
[b6]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
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[b6] Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [b6]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [b6] (USA) [b6]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [b6] Hughes, Eric [b6]; Jansen, Kathrin [b6]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Kim, Elizabeth [elkim@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Wachtel, Jonathan [jwachtel@DELOITTE.com]; Prabhavathi Fernandes [b6]; Diamond, Michael [b6]; Rose Li [b6] Dana Carluccio [b6] Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

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[b6]; Dave Frankowski [b6]; Baric, Toni C
[b6]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint
(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin
[bstratton@DELOITTE.com]

Subject: RE: ACTIV Preclinical working group (Tuesday meeting)

Attachments: PRECLINICAL_Working Group_Agenda_20200527_d2.pptx; 2020-05-22_Preclinical_WG_Summary_V1.docx

Hi all,

Please find attached our agenda for today's meeting and the summary notes from our Friday meeting.

Look forward to our discussion today.

Regards,
Joe and Rosa

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T] [b6]

Sent: Tuesday, April 14, 2020 6:44 PM

To: Menetski, Joseph (FNIH) [T]; [b6]

[b6]
[b6] Baric, Ralph [b6]; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine
(NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); [b6]
[b6] Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E];
[b6] Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas
Cihlar; [b6] (USA)

Cc: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy;
Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E];
Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa
Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana
Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C];
Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E];
Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin

Subject: ACTIV Preclinical working group (Tuesday meeting)

When: Wednesday, May 27, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: [b6]

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From: Alvarez, Rosa Maria [rosalvarez@deloitte.com]
Sent: 5/27/2020 1:44:57 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; [b6]
[b6]
[b6] Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; [b6]
Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
[b6] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];
[b6] Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [b6]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [b6] (USA) [b6]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [b6] Hughes, Eric [b6] Jansen, Kathrin [b6]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Kim, Elizabeth [elkim@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Wachtel, Jonathan [jwachtel@DELOITTE.com]; Prabhavathi Fernandes [b6]; Diamond, Michael [b6] Rose Li [b6]; Dana Carluccio [b6] Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D
[b6] Dave Frankowski [b6]; Baric, Toni C
[b6] Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint
(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin
[bstratton@DELOITTE.com]

Subject: RE: ACTIV Preclinical working group (Tuesday meeting)

Attachments: PRECLINICAL_Working Group_Agenda_20200527_d3.pptx

Hi all,

Apologies – attached is the agenda along with a preliminary overview of our Preclinical Mid-term Plan as well as an updated timeline for our discussion today.

Look forward to our discussion today.

Regards,
Rosa

Rosa M. Álvarez

Deloitte Consulting LLP

Mobile: [b6]

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From: Alvarez, Rosa Maria

Sent: Wednesday, May 27, 2020 8:17 AM

To: Menetski, Joseph (FNIH) [T]

[b6]
[b6] Ottinger,
Elizabeth (NIH/NCATS) [E] [b6] Colvis, Christine (NIH/NCATS) [E] [b6]
Hewitt, Judith (NIH/NIAID) [E] [b6]; Deming, Damon (FDA/CDER) [b6]
[b6]; Parker, Ashley (NIH/OD) [E]
[b6] Collins, Francis (NIH/OD) [E] [b6]
Adams, Peter (OS/ASPR/BARDA) [b6]; Rao, Srinivas [b6]; Qashu, Felicia
(NIH/OD) [E] [b6]; Tomas Cihlar [b6]
[b6] (USA) [b6]
Cc: Wholley, David (FNIH) [T] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]
Melencio, Cheryl (FNIH) [T] [b6]; Desrosiers, Betsy [b6]; Hughes, Eric
[b6]; Jansen, Kathrin [b6]; Kurilla, Michael (NIH/NCATS) [E]
[b6]; Lowy, Douglas (NCI) [b6]; Read, Sarah (NIH/NIAID) [E] [b6]
Tountas, Karen (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T]
[b6]; James, Stephanie (FNIH) [T] [b6]; Kim, Elizabeth <elkim@deloitte.com>; Tolman,
Brett <btolman@deloitte.com>; Wachtel, Jonathan <jwachtel@DELOITTE.com>; Prabhavathi Fernandes
[b6]; Diamond, Michael [b6] Rose Li
[b6]; Dana Carluccio [b6]; Lagos, Enrique (NIH/NCATS) [E]
[b6] onson, Samantha (NIH/NCATS) [E] [b6]; Gonzalez, Nina
<ningonzalez@deloitte.com>; Simon, Dina (NIH/OD) [C] [b6] Burrus-Shaw, Cyndi (NIH/OD) [E]
[b6] Rodriguez, Robin D [b6]; Dave Frankowski
[b6]; Baric, Toni C [b6]; Lowy, Douglas (NIH/NCI) [E]

[b6], Florence, Clint (NIH/NIAID) [E] [b6]; Nancy Haigwood
[b6], Stratton, Benjamin <bstratton@DELOITTE.com>

Subject: RE: ACTIV Preclinical working group (Tuesday meeting)

Hi all,

Please find attached our agenda for today's meeting and the summary notes from our Friday meeting.

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Regards,
Joe and Rosa

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T] [b6]

Sent: Tuesday, April 14, 2020 6:44 PM

To: Menetski, Joseph (FNIH) [T]; [b6]

[b6]
[b6] Baric, Ralph; [b6] Ottinger, Elizabeth (NIH/NCATS) [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); [b6]

[b6] Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E];
[b6] Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; [b6] (USA)

Cc: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin

Subject: ACTIV Preclinical working group (Tuesday meeting)

When: Wednesday, May 27, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: [b6]

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From: Tountas, Karen (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
Sent: 5/27/2020 5:52:13 PM
To: Bascles, Lionel [b6]; Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [b6]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers, Betsy [b6]; Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshow, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshoj]; Garner, Carlos [b6]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Mensah, George (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura [b6]; Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Vincent, Mike [b6]; Wachtel, Jonathan [jwachtel@deloitte.com]; Weinmann, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang]
CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [b6]; Jansen, Kathrin [b6]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [b6]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [marganderson@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Carluccio, Dana [b6]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny [b6]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [b6]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveson, Nancy [b6]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Criffield, Robin [b6]; Hamilton, Nancy [b6]; Melencio, Cheryl (FNIH) [T]

[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Minnich, Beth
[b6] Mueller-Reichenstein, Petra [b6] Pico, Dianna
(NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=471cb6a63c8846a69073e1e968f3964c-picodf]; Quadros, Nora
[b6]; Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Hill, Zoe (NIH/NHLBI) [C]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]

Subject: Summary and action items - CT Capacity WG meeting #12
Attachments: Clinical_Trial_Capacity_Working_Group_Meeting_12_Final.pdf

Dear Clinical Trial Capacity Working Group Members,

Attached is the summary and action items for meeting #12 (May 26, 2020) of the full working group. The next full working group meeting is scheduled for Friday, May 29 at 9 am eastern US time.

With best regards,
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health
[b6] fniih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fniih.org/pandemic



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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/27/2020 10:18:57 PM
To: Ruxandra Draghia-Akli [b6]; Naimish Patel [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [b6]; Keith Gottesdiener [b6]; Elliott Levy [b6]; Wung, Peter /US [b6]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [b6]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: Canceled: ACTIV TX-Clinical Agent Prioritization- mAb Subteam Meeting
Location: [b6]
Start: 5/28/2020 4:00:00 PM
End: 5/28/2020 5:00:00 PM
Show Time As: Free

Required Attendees: Read, Sarah (NIH/NIAID) [E]; Eric Hughes; Amanda Peppercorn; Breuer, Sebastian; Martin, Flavius; Andrew Charles
Optional Attendees: Adams; John Mellors; Marovich, Mary (NIH/NIAID) [E]; Judy Currier; Tressler, Randall (NIH/NIAID) [E]; Smith, David
Elizabeth Kim; Chen, Helen Q.; Payton, Natalie; Andrew Para; [b6]; Dana Carluccio; Lucas Smalldon;
Rose Li Central Account

Dear ACTIV TX-Clinical Agent Prioritization team,

Thank you all for your responses. We will be converting this meeting into a mAb Subteam meeting for tomorrow in the hope of finalizing the minimal entry criteria.

Thank you all for your flexibility and understanding.

Stacey

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[b6] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5dc9f31ded594eff8ac506d2c4103c15-ledgerwood]; [b6]
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[b6] Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33958e1252cf4266bffc8d94988f5715-kneuzil.com];
Offit, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cdb9cc56fdb4598a57b423d484dcf9f-offit.email]; [b6]
[b6] Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH)
[T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Laurent Humeau
[b6] Schrag, Stephanie (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9be29b344ba14363bdecaa43582ca226-ZHA6]; Verani, Jennifer R. (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c249692151d46d6ac80cb28ada3d3a0-qzr7]; Parker, Ashley (NIH/OD) [E]
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[b6] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E]
[b6] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Wachtel, Jonathan [jwachtel@DELOITTE.com]; Hotez, Peter Jay [b6]
[b6] Tal Zaks [b6]; Greg Glenn
[b6] Tolman, Brett [btolman@deloitte.com]
CC: [b6]
[b6] Johnson, Maureen (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr]; Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; Soriano Osejo, Douglas [b6]; Stratton, Benjamin [bstratton@DELOITTE.com]; Sitar, Sandra (NIH/VRC) [C]
[b6] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79e781b1f84a4f878583062a6ae87017-sitars]; Tong, Tina (NIH/NIAID) [E]
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbf6108d53148f684dad333fce983de-aarvin.stan]; Beth Bell [b6]; Cavaleri Marco [b6]; [b6] [b6] Haynes, Barton [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5d4a05845b5b4069ad0447fb60ebfa79-hayne002.mc]; [b6] [b6] Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=9be29b344ba14363bdecaa43582ca226-ZHA6]; Verani, Jennifer R. (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=0712e2a723d741e8a78c4c8d37724ba1-sallyh]; Follmann, Dean (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=42106b36984344e0914421f5fe408e7b-dfollmann]

Subject: REVIEW REQUESTED by Thursday, 8pm ET: NIAID DSMB membership

Attachments: NIAID DSMB suggested names.docx

Dear Vaccines Clinical Trials Sub-Group members (and cc'ing the Vaccines Working Group),

As mentioned in a previous email, NIAID is constituting a DSMB for the efficacy trials that are implemented with US government funding. They have collected 20 recommendations in the attached document (including some from this group), from which they plan to select 9 plus alternates in case not everyone accepts. They are looking for a specific mix of experience among the 9 (see header of the attachment).

Please review the document and provide any input you have on the proposed DSMB members by tomorrow (Thursday) at 8pm ET. Your feedback would be appreciated on any listed person that you would particularly recommend and any listed person that you would advise against inviting. We will share consolidated feedback from the group with Sally Hunsberger and Dean Follmann of NIAID; your individual feedback will not be shared.

Sally and Dean plan to join the start of our meeting tomorrow to answer any questions about the process, but we do not plan to discuss opinions about individuals in the meeting.

Please let us know if you have any questions. We look forward to your input.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science
Foundation for the National Institutes of Health

b6

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
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To: Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Sandeep Menon [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price [b6]; Eron, Joe [b6]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; [b6] Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]
CC: Demarcus [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa [b6]; Eron, Joseph J Jr [b6]; Smith, David [b6]; Paul Klekotka [b6]; Ajay Nirula [b6]; Chen, Helen Q. [qingchen@deloitte.com]
Subject: Agenda for ACTIV-2 Writing Team Meeting
Attachments: ACTIV_TX-Clinical_ACTIV-2 Writing Team Meeting Agenda_05282020.pdf

Dear ACTIV-2 Writing Team,

Please find attached the proposed agenda for tomorrow's meeting. We may also have some outcomes and slides to share from the stats meeting preceding this, but those will be distributed after that call.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
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Subject: ACTIV-2 Writing Team Meeting

Attachments: ACTIV_TX-Clinical_ACTIV-2 Writing Team Meeting Agenda_05282020.pdf

Location: [b6]

Start: 5/28/2020 3:00:00 PM

End: 5/28/2020 4:00:00 PM

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Required Attendees: Judy Currier; Eric Hughes; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; [b6]; Eron, Joe; Javan, Arzhang (NIH/NIAID) [E]; Roa, Jhoanna; [b6]; Kim, Peter (NIH/NIAID) [E]; Kozak, Marina (OS/ASPR/BARDA)
Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Jhoanna Roa; Eron, Joseph J Jr; Smith, David; Paul Klekotka; Ajay Nirula; Chen, Helen Q.

Dear ACTIV-2 Writing Team,

Please find attached the proposed agenda for tomorrow's meeting. We may also have some outcomes and slides to share from the stats meeting preceding this, but those will be distributed after that call.

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Thanks,
Stacey

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To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [b6]; Eisner, Mark [b6]; Gottesdiener, Keith [b6]; Hughes, Eric [b6]; Judy Carrier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [elkim@deloitte.com]; LaVange, Lisa [b6]; Levy, Elliot [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [b6]; Peppercorn, Amanda [b6]; Poole, Mike [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coll]; Amanda Peppercorn [b6]; Garner, Carl [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Burgess, Timothy [b6]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-roosenbey]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [b6]; Jansen, Kathrin [b6]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John
 [b6]; Biggs, Mary [b6]; Butcher, Tina [b6]
 [b6]; Macone, Erin [b6] Melencio, Cheryl (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla
 [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH)
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan
 [jwachtel@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Alvarez, Rosa [rosalvarez@deloitte.com];
 Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [b6] Rose
 Li Central Account [FNIH@roseliassociates.com]; Anderson, Margaret [marganderson@deloitte.com]; Lucas
 Smalldon [b6]; Stratton, Benjamin [bstratton@DELOITTE.com];
 [b6] m; Mollica, Linda /US [b6]; Qashu, Felicia (NIH/OD) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Goff, David (NIH/NHLBI) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Rubin, Daniel B. (FDA/CDER)
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary
 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Hoots, W. Keith
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Mensah, George
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Kiley, James (NIH/NHLBI)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Groesch, Mary (NIH/NHLBI) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]

Subject: ACTIV TX-Clinical Working Group Meeting #8

Attachments: ACTIV_TX-Clinical_Working Group Meeting Guide_20200528.pdf

Location: [b6]

Start: 5/28/2020 5:00:00 PM

End: 5/28/2020 6:00:00 PM

Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]

Optional Attendees: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla;

Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; **b6** Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] **b6**; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Hoots, W. Keith (NIH/NHLBI) [E]; Mensah, George (NIH/NHLBI) [E]; Kiley, James (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]

Dear TX-Clinical WG,

Please find attached the slides for the meeting today. We will have some slight updates on the mAb criteria to discuss, but otherwise these are what we will use to review.

Thanks,

Stacey

Join Zoom Meeting

b6

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From: Eron, Joseph J Jr [b6]
Sent: 5/28/2020 6:45:14 PM
To: Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [b6] LaVange, Lisa M [b6]; Sandeep Menon [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price [b6]
[b6] Wohl, David A [b6] Fischer, William A. II [b6]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; [b6] Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Carlos O Garner [b6]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]
CC: DeMarcus, Forrest [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jhoanna Roa [b6]; Smith, David [b6]; L. Paul Klekotka [b6]; Ajay Nirula [b6]; Lucas Smalldon [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [b6]; Chen, Helen Q. [qingchen@deloitte.com]
Subject: RE: ACTIV-2 Writing Team and mAb Steering Committee Joint Meeting - Protocol Update

I was referring to the paper and its implications for infectiousness

I think development of a quantitative assay with internal standards that will allow for more precise quantitation beyond just cycle number which might vary between assay runs is the way to go.

Joseph J. Eron MD
Professor of Medicine
Chief, Infectious Diseases Division

b6

Admin: Nate_Cooper@med.unc.edu

From: Marks, Gilbert (OS/ASPR/BARDA) (CTR) **b6**

Sent: Thursday, May 28, 2020 2:41 PM

To: Eron, Joseph J Jr **b6**; Bozzette, Sam (NIH/NCATS) [E] **b6** Adam, Stacey (FNIH) [T] **b6** Judy Currier **b6**; Eric Hughes **b6** LaVange, Lisa M **b6**; Sandeep Menon **b6**; Proschan, Michael (NIH/NIAID) [E] **b6**; Read, Sarah (NIH/NIAID) [E] **b6** Price, Dionne (FDA/CDER) **b6**; Rubin, Daniel B. (FDA/CDER) **b6**; Farley, John (FDA/CDER) **b6**; Karen Lynn Price **b6**; Wohl, David A **b6**; Fischer, William A. II **b6**; Javan, Arzhang (NIH/NIAID) [C] **b6** Roa, Johanna **b6** Kim, Peter (NIH/NIAID) [E] **b6**; Butterson, Joan **b6**; Higgs, Elizabeth (NIH/NIAID) [E] **b6** Woodcock, Janet (FDA/CDER) **b6**; Stein, Peter (FDA/CDER) **b6** Carlos O Garner **b6**; Bugin, Kevin (FDA/CDER) **b6**; Kozak, Marina (OS/ASPR/BARDA) **b6**
Cc: DeMarcus, Forrest **b6** Tountas, Karen (FNIH) [T] **b6**; Wachtel, Jonathan <jwachtel@deloitte.com>; Elizabeth Kim <elkim@deloitte.com>; Parker, Ashley (NIH/NCI) [E] **b6** Johanna Roa **b6** Smith, David **b6**; Paul Klekotka **b6**; Ajay Nirula **b6**; Lucas Smalldon **b6**; Rose Li Central Account <FNIH@roseliassociates.com>; Dana Carluccio Chen, Helen Q. <qingchen@deloitte.com>

Subject: RE: ACTIV-2 Writing Team and mAb Steering Committee Joint Meeting - Protocol Update

Thanks Joe

Cycle thresholds will be important to specify I would suggest. Amplifying non-infectious fragments vs correlating with what would suggest infectious virus begs for at least standardization of Ct. Or am I missing your point that we shouldn't bother with setting Ct...as long as it can be amplified no matter how many cycles, it would still be a positive? CDC colleagues may have more on this issue.

Lynn

From: Eron, Joseph J Jr **b6**

Sent: Thursday, May 28, 2020 12:25 PM

To: Bozzette, Sam (NIH/NCATS) [E] **b6**; Adam, Stacey (FNIH) [T] **b6** Judy Currier **b6**; Eric Hughes **b6**; LaVange, Lisa M **b6**; Sandeep Menon **b6**; Proschan, Michael (NIH/NIAID) [E] **b6**; Read, Sarah (NIH/NIAID) [E] **b6**; Price, Dionne (FDA/CDER) **b6**; Rubin, Daniel B. (FDA/CDER) **b6**; Farley, John (FDA/CDER) **b6** Karen Lynn Price **b6**; Wohl, David A **b6**; Fischer, William A. II **b6**; Javan, Arzhang (NIH/NIAID) [C] **b6** Roa, Johanna **b6** Kim, Peter (NIH/NIAID) [E] **b6**; Butterson, Joan **b6**; Higgs, Elizabeth (NIH/NIAID) [E] **b6** Woodcock, Janet (FDA/CDER) **b6**; Stein, Peter (FDA/CDER) **b6** Carlos O Garner **b6**; Bugin, Kevin (FDA/CDER) **b6**; Marks, Gilbert (OS/ASPR/BARDA)

(CTR) [b6]; Kozak, Marina (OS/ASPR/BARDA) [b6]
Cc: DeMarcus, Forrest [b6]; Tountas, Karen (FNIH) [T] [b6]; Wachtel, Jonathan <jwachtel@deloitte.com>; Elizabeth Kim <elkim@deloitte.com>; Parker, Ashley (NIH/NCI) [F] [b6]; Jhoanna Roa [b6]; Smith, David [b6]; Paul Klekotka [b6]; Ajay Nirula [b6]; Lucas Smalldon [b6]; Rose Li Central Account <FNIH@roseliassociates.com>; Dana Carluccio Chen, Helen Q. <qingchen@deloitte.com>
Subject: Re: ACTIV-2 Writing Team and mAb Steering Committee Joint Meeting - Protocol Update

I don't find this particularly reassuring. As you know it is extremely difficult to culture HIV from semen but there is no doubt about its infectiousness

Joseph Eron MD
Professor of Medicine
Division of Infectious Disease
UNC Chapel Hill

[b6]

From: Bozzette, Sam (NIH/NCATS) [E] [b6]
Sent: Thursday, May 28, 2020 11:45:50 AM
To: Adam, Stacey (FNIH) [T] [b6]; Judy Currier [b6]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Sandeep Menon [b6]; Proschan, Michael (NIH/NIAID) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Price, Dionne (FDA/CDER) [b6]; Rubin, Daniel B. (FDA/CDER) [b6]; Farley, John (FDA/CDER) [b6]; Karen Lynn Price [b6]
[b6]
[b6]; Wohl, David A [b6]; Fischer, William A. II [b6]; Eron, Joseph J Jr [b6]; Javan, Arzhang (NIH/NIAID) [E] [b6]; Roa, Jhoanna [b6]; Kim, Peter (NIH/NIAID) [b6]; Butters, Joan [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6]; Woodcock, Janet (FDA/CDER) [b6]; Stein, Peter (FDA/CDER) [b6]; Carlos O Garner [b6]; Bugin, Kevin (FDA/CDER) [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]; Kozak, Marina (OS/ASPR/BARDA) [b6]
Cc: DeMarcus, Forrest [b6]; Tountas, Karen (FNIH) [T] [b6]; Wachtel, Jonathan <jwachtel@deloitte.com>; Elizabeth Kim <elkim@deloitte.com>; Parker, Ashley (NIH/OD) [E] [b6]; Jhoanna Roa [b6]; Eron, Joseph J Jr [b6]; Smith, David [b6]; Paul Klekotka [b6]; Ajay Nirula [b6]; Lucas Smalldon [b6]; Rose Li Central Account <FNIH@roseliassociates.com>; Dana Carluccio Chen, Helen Q. <qingchen@deloitte.com>
Subject: RE: ACTIV-2 Writing Team and mAb Steering Committee Joint Meeting - Protocol Update

Of interest re interpreting virology - [b6]

-----Original Appointment-----

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Saturday, May 23, 2020 1:02 PM
To: Adam, Stacey (FNIH) [T]; Judy Currier; Eric Hughes; LaVange, Lisa M; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price [b6]

b6

Eron, Joe; Javan, Arzhang (NIH/NIAID) [E]; Roa, Jhoanna;

b6

Kim, Peter (NIH/NIAID) [E]; Bozzette, Sam (NIH/NCATS) [E]; Butters, Joan; Higgs, Elizabeth

(NIH/NIAID) [E]; Woodcock, Janet (FDA/CDER); Stein, Peter (FDA/CDER); Carlos O Garner; Bugin, Kevin (FDA/CDER); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Kozak, Marina (OS/ASPR/BARDA)

Cc: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Jhoanna Roa; Eron, Joseph J Jr; Smith, David; Paul Klekotka; Ajay Nirula; Lucas Smalldon; Rose Li Central Account; Dana Carluccio; Chen, Helen Q.

Subject: ACTIV-2 Writing Team and mAb Steering Committee Joint Meeting - Protocol Update

When: Wednesday, May 27, 2020 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: **b6**

Dear ACTIV-2 Writing Team and ACTIV mAb Steering Committee,

We are looking forward to this joint meeting tomorrow in which the ACTIV-2 team will share their progress on the mAb outpatient master protocol with the Steering Committee. The team will review the current thinking within the protocol. Then they would like to solicit feedback from the Steering Committee about a few remaining questions that could still alter the protocol structure.

Please find attached the materials for tomorrow:

1. Meeting agenda
2. Current ACTIV-2 master protocol
3. Slides summarizing the current protocol

Please note that the stats team is still working to insert the final design of the Bayesian framework that will be used for agents beyond the first drug(s) into the trial for progression from Phase 2 to 3 within the study. This framework will not apply to the early entrants since prior learnings will be needed to inform the Bayesian model.

In addition, the team is waiting on some critical feedback from the FDA about how to address company feedback for a Phase 1(ish) safety/dose "run-in" study protocol that could be paired with the master protocol and potentially be overseen by ACTIV.

Thanks,
Stacey

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CC: Demarcus [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jhoanna Roa [b6]; Eron, Joseph J Jr [b6]; Smith, David [b6]; Paul Klekotka [b6]; Ajay Nirula [b6]; Lucas Smalldon [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [b6]; Chen, Helen Q. [qingchen@deloitte.com]
Subject: Summary from ACTIV-2 Writing Team and mAb Steering Committee Joint Meeting
Attachments: 2020-05-27_TX-Clinical_WG_ACTIV-2_Writing Team_mAb_SC_Summary.pdf

Dear ACTIV-2 Writing Team and ACTIV mAb Steering Committee,

Thank you so much for a very productive meeting with the ACTIV-2 team yesterday. I think we were able to make a lot of head way on the outstanding protocol decisions which helped the team refine further today on their call.

APAR0000005264

For your reference, please find attached the formal summary to the meeting. If you have additions or amendments, please contact me and I will make them.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

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[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John
[b6]

Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting
Attachments: Clinical Trial Capacity Working Group Meeting Agenda_05292020.pdf
Location: [b6]

Start: 5/29/2020 1:00:00 PM
End: 5/29/2020 2:00:00 PM
Show Time As: Tentative

Recurrence: Weekly
every Tuesday and Friday from 9:00 AM to 10:00 AM
Required Attendees: Garner, Carlos; Bascles, Lionel; Vincent, Mike; Payton, Manzone; Cohen, Myron; Corey, Larry; Davey, Victoria;
Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshov, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; Kurilla,
Mike; Nayak, Seema (NIH/NIAID) [E]; Qashu, Felicia; Resnansky, Laura; Sizemore, Christine (NIH/FIC) [E]; Srinivasan,
Badhri; Stein, Peter (FDA/CDER); Wachtel, Jonathan; Mensah, George; Weinmann, Gail
Optional Attendees: Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Kublin MD, MPH, James; Ferguson, Sue; Kenny, Dermot;
Gonzalez, Nina; Criffield, Robin; Hamilton, Nancy; Melencio, Cheryl (FNIH) [T]; Minnich, Beth; Mueller-Reichenstein,
Petra; Quadros, Nora; Rebecca (NIH/NCATS) Katz [E] [b6]; Zoe (NIH/NHLBI) Hill [C]
[b6]; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Ashley (NIH/OD) Parker [E]
[b6] Carluccio, Dana; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T];
Santos, Michael (FNIH); Tuveson, Nancy; Wholley, David (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric;
Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John

Colleagues – Attaching the agenda for the call. Best, Karen

Dear Clinical Trial Capacity WG members, This will extend our full working group calls through the end of May. We'll assess the need for further meetings at the end of the month. Many thanks for your participation! Karen

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Subject: ACTIV TX-Clinical Working Group Meeting #9

Location: [b6]

Start: 6/4/2020 5:00:00 PM

End: 6/4/2020 6:00:00 PM

Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] [b6]; Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]

Optional Attendees: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin [b6]; Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/29/2020 1:28:31 AM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E]; [b6] Butterson, Joan [b6]; De Claro, R. Angelo (FDA/CDER) [b6]; Draghia-Akli, Ruxandra [b6]; Eisner, Mark [b6]; Gottesdiener, Keith [b6]; Hughes, Eric [b6]; Judy Currier [b6]; Kim, Elizabeth [elkim@deloitte.com]; LaVange, Lisa [b6]; Levy, Elliot [b6]; Mellors, John W [b6] Menon, Sandeep [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [b6]; Peppercorn, Amanda [b6]; Poole, Mike [b6]; Proschan, Michael (NIH/NIAID) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Santos, Michael (FNIH) [T] [b6]; Shen, Yuan Li (FDA/CDER) [b6]; Stein, Peter (FDA/CDER) [b6]; Wholley, David (FNIH) [T] [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [b6]; Collins, Sylva (FDA/CDER) [b6]; Amanda Peppercorn [b6]; Garner, Carl [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6]; Koroshetz, Walter (NIH/NINDS) [E] [b6]; Timothy Burgess [b6]; Reineck, Lora (NIH/NHLBI) [E] [b6]; Aggarwal, Neil (NIH/NHLBI) [E] [b6]; Rosenberg, Yves (NIH/NHLBI) [E] [b6]; Goff, David (NIH/NHLBI) [E] [b6]; Brown, Jeremy (NIH/NINDS) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Culp, Michelle (NIH/OD) [E] [b6]; Jacqueline Kirchner [b6]
CC: Colvis, Christine (NIH/NCATS) [E] [b6]; Desrosiers, Betsy [b6]; Jansen, Kathrin [b6]; Kurilla, Michael (NIH/NCATS) [E] [b6]; Lowy, Douglas (NCI) [b6]; Young, John [b6]; Biggs, Mary [b6]; Butcher, Tina [b6]; Demarcus [b6]; Macone, Erin [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Salathin, Carla [b6]; Tountas, Karen (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]; James, Stephanie (FNIH) [T] [b6]; Wachtel, Jonathan [jwachtel@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Alvarez, Rosa [rosalvarez@deloitte.com]; Gonzalez, Nina [ningonzalez@deloitte.com]; Dana Carluccio [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Anderson, Margaret [marganderson@deloitte.com]; Lucas Smalldon [b6]; Stratton, Benjamin [bstratton@DELOITTE.com]; [b6]; Mollica, Linda /US [b6]; Qashu, Felicia (NIH/OD) [E] [b6]; Patterson, Amy (NIH/NHLBI) [E] [b6]; Rubin, Daniel B. (FDA/CDER) [b6]; Marston, Hilary (NIH/NIAID) [E] [b6]; Chen, Helen Q. [b6]; Wung, Peter /US [b6]; Hoots, W. Keith (NIH/NHLBI) [E] [b6]

Subject: ACTIV TX-Clinical Working Group Meeting #9
Attachments: ACTIV_TX-Clinical_Working Group Meeting Guide_20200604.pdf
Location: [b6]

Start: 6/4/2020 5:00:00 PM
End: 6/4/2020 6:00:00 PM
Show Time As: Busy

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E];

**Optional
Attendees:**

Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] **b6**
Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner
Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas
(NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla;
Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman,
Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon;
Stratton, Benjamin; jennifer.j.palmer@pfizer.com; Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy
(NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US;
Hoots, W. Keith (NIH/NHLBI) [E]

Dear ACTIV TX-Clinical WG,

Please find attached the slides for tomorrow's meeting which contain the agenda. We will be using this meeting as last week to update on the progress of the master protocol groups and the mAb subteam from the Agent Prioritization group.

Please let us know if there is anything else you feel the team needs to discuss.

Thanks,
Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/29/2020 1:28:32 AM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [b6]; Butterton, Joan [b6]; De Claro, R. Angelo (FDA/CDER) [b6]; Draghia-Akli, Ruxandra [b6]; Eisner, Mark [b6]; Gottesdiener, Keith [b6]; Hughes, Eric [b6]; Judy Currier [b6]; Kim, Elizabeth [elkim@deloitte.com]; LaVange, Lisa [b6]; Levy, Elliot [b6]; Mellors, John W [b6]; Menon, Sandeep [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Patel, Naimish [b6]; Peppercorn, Amanda [b6]; Poole, Mike [b6]; Proschan, Michael (NIH/NIAID) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Santos, Michael (FNIH) [T] [b6]; Shen, Yuan Li (FDA/CDER) [b6]; Stein, Peter (FDA/CDER) [b6]; Wholley, David (FNIH) [T] [b6]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [b6]; Collins, Sylva (FDA/CDER) [b6]; Amanda Peppercorn [b6]; Garner, Carl [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6]; Koroshetz, Walter (NIH/NINDS) [E] [b6]; Timothy Burgess [b6]; Reineck, Lora (NIH/NHLBI) [E] [b6]; Aggarwal, Neil (NIH/NHLBI) [E] [b6]; Rosenberg, Yves (NIH/NHLBI) [E] [b6]; Goff, David (NIH/NHLBI) [E] [b6]; Brown, Jeremy (NIH/NINDS) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [b6]; Jacqueline Kirchner [b6]
CC: Colvis, Christine (NIH/NCATS) [E] [b6]; Desrosiers, Betsy [b6]; Jansen, Kathrin [b6]; Kurilla, Michael (NIH/NCATS) [E] [b6]; Lowy, Douglas (NCI) [b6]; Young, John [b6]; Biggs, Mary [b6]; Butcher, Tina [b6]; Demarcus [b6]; Macone, Erin [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Salathin, Carla [b6]; Tountas, Karen (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]; James, Stephanie (FNIH) [T] [b6]; Wachtel, Jonathan [jwachtel@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Alvarez, Rosa [rosalvarez@deloitte.com]; Gonzalez, Nina [ningonzalez@deloitte.com]; Dana Carluccio [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Anderson, Margaret [marganderson@deloitte.com]; Lucas Smalldon [b6]; Stratton, Benjamin [bstratton@DELOITTE.com]; [b6].com; Mollica, Linda /US [b6]; Qashu, Felicia (NIH/OD) [E] [b6]; Patterson, Amy (NIH/NHLBI) [E] [b6]; Rubin, Daniel B. (FDA/CDER) [b6]; Marston, Hilary (NIH/NIAID) [E] [b6]; Chen, Helen Q. [qingchen@deloitte.com]; Wung, Peter /US [b6]; Hoots, W. Keith (NIH/NHLBI) [E] [b6]
Subject: ACTIV TX-Clinical Working Group Meeting #9
Attachments: ACTIV_TX-Clinical_Working Group Meeting Guide_20200604.pdf
Location: [b6]

Start: 6/4/2020 5:00:00 PM
End: 6/4/2020 6:00:00 PM
Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Butterton, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E];

Optional Attendees: Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; b6; Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; jennifer.j.palmer@pfizer.com; Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]

Dear ACTIV TX-Clinical WG,

Please find attached the slides for tomorrow's meeting which contain the agenda. We will be using this meeting as last week to update on the progress of the master protocol groups and the mAb subteam from the Agent Prioritization group.

Please let us know if there is anything else you feel the team needs to discuss.

Thanks,
Stacey

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Sent: 5/29/2020 1:31:49 AM
To: Jim Neaton [b6]; Jens Lundgren [b6]; Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; LaVange, Lisa M [b6]; Karen Lynn Price [b6]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Carlos O Garner [b6]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]
CC: Chen, Helen Q. [b6]; Demarcus [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Salathin, Carla [b6]

Subject: ACTIV-3 Writing Team and mAb Steering Committee Joint Meeting

Location: [b6]

Start: 6/5/2020 4:00:00 PM

End: 6/5/2020 5:00:00 PM

Show Time As: Tentative

Required Attendees: Jim Neaton; Jens Lundgren; Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Kozak, Marina (OS/ASPR/BARDA); Patterson, Amy (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Judy Currier; Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Lisa LaVange; Karen Lynn Price; Woodcock, Janet (FDA/CDER); Stein, Peter (FDA/CDER); Carlos O Garner; Bugin, Kevin; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Farley, John (FDA/CDER)

Optional Attendees: Chen, Helen Q.; Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Parker, Ashley (NIH/OD) [E]; Salathin, Carla

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
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To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Jim Neaton [b6]; Jens Lundgren [b6]; Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6]; Kozak, Marina (OS/ASPR/BARDA) [b6]; Patterson, Amy (NIH/NHLBI) [E] [b6]; Aggarwal, Neil (NIH/NHLBI) [E] [b6]; Reineck, Lora (NIH/NHLBI) [E] [b6]; Judy Currier [b6]; Bozzette, Sam (NIH/NCATS) [E] [b6]; LaVange, Lisa M [b6]; Karen Lynn Price [b6]; Woodcock, Janet (FDA/CDER) [b6]; Stein, Peter (FDA/CDER) [b6]; Carlos O Garner [b6]; Bugin, Kevin (FDA/CDER) [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]; Farley, John (FDA/CDER) [b6]; Miller, Marissa A (NIH/NHLBI) [E] [b6]; Rachel Harrigan [b6]; William Erhardt [b6]; Gelijns, Annetine [b6]; Moskowitz, Alan [b6]; Ab Babiker [b6]; Cavan, Reilly [b6]; Phillips, Andrew [b6]; Birgit Grund [b6]; Neaton, Jim [b6]; Joe Koopmeiners [b6]; David Vock [b6]; Thomas Murray [b6]; Max Parmar [b6]; Mark Polizzotto [b6]; Ginny Kan [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Roger Paredes [b6]; Rosenberg, Yves (NIH/NHLBI) [E] [b6]; Joan Butterson [b6]; Baker, Jason [b6]; Chen, Helen Q. [qingchen@deloitte.com]; Demarcus [b6]; Tountas, Karen (FNIH) [T] [b6]; Wachtel, Jonathan [jwachtel@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Salathin, Carla [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Lucas Smalldon [b6]; Dana Carluccio [b6]; Bagiella, Emilia [b6]
CC:
Subject: ACTIV-3 Writing Team and mAb Steering Committee Joint Meeting
Attachments: ACTIV_TX-Clinical_ACTIV-3 mAb Steering Committee Meeting Agenda_20200605.pdf
Location: [b6]
Start: 6/5/2020 3:30:00 PM
End: 6/5/2020 4:30:00 PM
Show Time As: Busy

Required Attendees: Jim Neaton; Jens Lundgren; Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Kozak, Marina (OS/ASPR/BARDA); Patterson, Amy (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Reineck, Lora (NIH/NHLBI) [E]; Judy Currier; Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Lisa LaVange; Karen Lynn Price; Woodcock, Janet (FDA/CDER); Stein, Peter (FDA/CDER); Carlos O Garner; Bugin, Kevin; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Farley, John (FDA/CDER); Miller, Marissa A (NIH/NHLBI) [E]; Rachel Harrigan; William Erhardt; [b6]; Gelijns, Annetine; Moskowitz, Alan; Ab Babiker; Cavan, Reilly; Phillips, Andrew [b6]; Birgit Grund; Neaton, Jim; Joe Koopmeiners; David Vock; Thomas Murray; Max Parmar; Mark Polizzotto; Ginny Kan; Lane, Cliff (NIH/NIAID) [E]; Baker, Jason; Roger Paredes; [b6]; Rosenberg, Yves (NIH/NHLBI) [E]; [b6]
Optional Attendees: Chen, Helen Q.; Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Parker, Ashley (NIH/OD) [E]; Salathin, Carla; Rose Li Central Account; Lucas Smalldon; Dana Carluccio; Bagiella, Emilia

Dear mAb Steering Committee and ACTIV-3 Writing Team,

Please find attached the agenda for tomorrow. The ACTIV-3 team is diligently working to incorporate the feedback from today into the latest version of the protocol outline. Once they circulate this latest version I will send to this group tomorrow for review.

Thanks,
Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/29/2020 3:02:44 AM
To: Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Sandeep Menon [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price [b6]; Eron, Joe [b6]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; [b6]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]
CC: Demarcus [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa [b6]; Eron, Joseph J Jr [b6]; Smith, David [b6]; Paul Klekotka [b6]; Ajay Nirula [b6]; Chen, Helen Q. [qingchen@deloitte.com]
Subject: Follow-up on ACTIV-2 Writing Team Meeting
Attachments: ACTIV_Therapeutics-Clinical_Master Protocol Subgroup_ACTIV-2 Writing Team Meeting_20200528.pdf; 2020-05-27_TX-Clinical_WG_ACTIV-2_Writing Team_mAb_SC_Summary.pdf

Dear ACTIV-2 Writing Team,

Thank you all for a very productive meeting. I think we are making good head way on the protocol. Looking forward to sharing it with the companies and FDA next week for feedback.

Please find the notes from the meeting today. If you have any additions or amendments, let us know. In addition, please find the summary of the joint meeting with the mAb Steering Committee from yesterday. Take note of the minimal data that FDA mentions for entering Phase 2. I thought John's take was helpful.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health

APAR0000005260-2442850

Direct: **b6** | Mobile: **b6**

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/29/2020 3:41:29 AM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [b6]; LaVange, Lisa M [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Karen Lynn Price [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Carlos O Garner [b6]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]
CC: Demarcus [b6] Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Chen, Helen Q. [qingchen@deloitte.com]; Salathin, Carla [b6]

Subject: ACTIV mAb Steering Committee Meeting

Attachments: ACTIV_TX-Clinical_mAb Steering Committee Meeting_20200529.pdf

Location: [b6]

Start: 5/29/2020 6:00:00 PM

End: 5/29/2020 7:00:00 PM

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Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Judy Currier; Eric Hughes; Lisa LaVange; Read, Sarah (NIH/NIAID) [E]; Karen Lynn Price; Higgs, Elizabeth (NIH/NIAID) [E]; Woodcock, Janet (FDA/CDER); Stein, Peter (FDA/CDER); Carlos O Garner; Bugin, Kevin; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Farley, John (FDA/CDER)
Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Chen, Helen Q.; Salathin, Carla

Dear mAb Steering Committee,

Please find attached the proposed agenda and slides for tomorrow. Please let us know if we need to add anything else to the agenda.

Thanks,
Stacey

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From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 5/29/2020 2:36:53 PM
To: Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
Subject: FW: [-EXTERNAL-] Invitation to speak at BIO Virtual International Convention (390956)
Attachments: BIO_Dr Collins Keynote Invite.pdf

Is this good enough? Seems like they ought to try a little harder.

From: Allen-Gifford, Patrice (NIH/OD) [E] [b6]
Sent: Friday, May 29, 2020 10:16 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Wood, Gretchen (NIH/OD) [E] [b6]
McManus, Ayanna (NIH/OD) [E] [b6]; Twyman, Leslie (NIH/OD) [E] [b6]
Coley, Gwendolyn (NIH/OD) [C] [b6]
Subject: FW: [-EXTERNAL-] Invitation to speak at BIO Virtual International Convention (390956)

FC, we asked BIO to make the panel in which they invited you to participate more inclusive. Below is the result—not sure if this one addition=inclusivity.

From: Sarah Arth [b6]
Sent: Friday, May 29, 2020 9:52 AM
To: Allen-Gifford, Patrice (NIH/OD) [E] [b6]; Phyllis Arthur [b6]
Cc: NIH Director Invitations <NIHDirectorInvitations@nih.gov>
Subject: RE: [-EXTERNAL-] Invitation to speak at BIO Virtual International Convention (390956)

Patrice,

My apologies for the delayed response. Below is the updated panel. We are pleased with the representation and hope that Dr. Collins can join us. Please do let me know.

Leveraging Platforms and Partnerships to Develop COVID-19 Vaccines in Record Time Tuesday, June 9, 11:30 AM – 12:30 PM PT

As numerous vaccines move through clinical development there are important issues that need to be addressed. How will companies and partners conduct global clinical trials? What are the key scientific issues that must be addressed to vaccinate millions of people worldwide? This panel will discuss the complex path to clinical trials, the impact of the evolving science on their development and share their thoughts on how collaboration will bring life-saving vaccines to the world.

Moderator: Mark McClellan, MD, Director, Duke Margolis Center for Health Policy

Panelists:

- Gregory Glenn, MD, Chief Scientific Officer, Novavax
- Margaret Hamburg, MD, Foreign Secretary, National Academy of Medicine
- Peter Marks, MD, PhD, Director, Center for Biologics Evaluation and Research, United States Food and Drug Administration
- Gary Nabel, MD. PhD, Chief Scientific Officer, Sanofi (invited)

- Paul Stoffels, MD, Vice Chairman of the Executive Committee and Chief Scientific Officer, Johnson & Johnson

Sarah S. Arth, CAE
Vice President, Education
Biotechnology Innovation Organization

O - [b6]
M - [b6]

From: Allen-Gifford, Patrice (NIH/OD) [E] [b6]
Sent: Friday, May 29, 2020 9:33 AM
To: Sarah Arth [b6]; Phyllis Arthur [b6]
Cc: NIH Director Invitations <NIHDirectorInvitations@nih.gov>
Subject: [-EXTERNAL-] Invitation to speak at BIO Virtual International Convention (390956)
Importance: High

Good day,

I am writing to you in follow up to Mr. Greenwood's message to me earlier this week. Do you have any further information that we may share with Dr. Collins?

With kind regards,

Patrice Allen-Gifford
Director
Executive Secretariat
National Institutes of Health
One Center Drive, B1-46
Bethesda, MD 20892
Tel: [b6]
Cell: [b6]

From: James C. Greenwood [b6]
Sent: Sunday, May 24, 2020 6:10 PM
To: Allen-Gifford, Patrice (NIH/OD) [E] [b6]
Cc: Sarah Arth [b6]; Twyman, Leslie (NIH/OD) [E] [b6]; NIH Director Invitations <NIHDirectorInvitations@nih.gov>; Phyllis Arthur [b6]
Subject: RE: [-EXTERNAL-] FW: For FC Decision: Invitation to speak at BIO Virtual International Convention (390956)

Thank you, Patrice. I believe we have already managed to do this. My staff will respond to you.

From: Allen-Gifford, Patrice (NIH/OD) [E] [b6]
Sent: Sunday, May 24, 2020 5:56 PM
To: James C. Greenwood [b6]
Cc: [b6]; Twyman, Leslie (NIH/OD) [E] [b6]; NIH Director Invitations <NIHDirectorInvitations@nih.gov>
Subject: Invitation to speak at BIO Virtual International Convention

Dear Mr. Greenwood,

Dr. Collins received your invitation to speak as part of a three-part plenary at BIO's virtual convention on June 11 and has asked me to thank you for inviting him to participate in this important and timely discussion on Leveraging Platforms and Partnership to Develop COVID-19 vaccines. As you may know, Dr. Collins is very committed and devoting enormous time to just such a unique effort, known as ACTIV. He would like to contribute to the BIO panel discussion, however, he has also committed to inclusiveness and ensuring a level playing field in speaking opportunities; he issued a statement outlining his commitment last year. The panel proposed in your invitation letter does not reflect that diversity. May we ask if there is a possibility of creating a more inclusive panel of speakers? Thank you again for thinking of Dr. Collins and NIH.

Most respectfully,

Patrice Allen-Gifford
Director
Executive Secretariat
National Institutes of Health
Cell: [b6]

From: James C. Greenwood [b6]
Sent: Thursday, May 14, 2020 5:59 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: [b6]
Subject: Dr. Collins - Invitation to speak at BIO Virtual International Convention

Dear Francis,

I hope this email finds you well. Thanks for your grand leadership in this awful time. Given the current environment, we have taken our annual BIO International Convention to a digital format this year. COVID-19 will be at the forefront of the content that we are planning for the event and we would like to invite you to participate in our three-part plenary, *A Way Forward: Winning the War on COVID through Vaccines*. I have attached a formal invite with complete session details. The session will take place on Tuesday, June 9 from 2:30 PM – 3:30 PM ET virtually. We hope that you can join us.

I look forward to your response.

All the best,

From: Tabak, Lawrence (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02E22836B5FF4E9988E3770CFC7EE770-TABAKL]
Sent: 5/29/2020 2:39:36 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
Subject: Re: [-EXTERNAL-] Invitation to speak at BIO Virtual International Convention (390956)
Flag: Follow up

No it is not adequate. In fact it is insulting.

From: Francis Collins [b6]
Date: Friday, May 29, 2020 at 10:36 AM
To: "Wolinetz, Carrie (NIH/OD) [E]" [b6]
Cc: "Tabak, Lawrence (NIH/OD) [E]" [b6]
Subject: FW: [-EXTERNAL-] Invitation to speak at BIO Virtual International Convention (390956)

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Sent: Friday, May 29, 2020 10:16 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Wood, Gretchen (NIH/OD) [E] [b6]; McManus, Ayanna (NIH/OD) [E] [b6]; Twyman, Leslie (NIH/OD) [E] [b6]; Coley, Gwendolyn (NIH/OD) [C] [b6]
Subject: FW: [-EXTERNAL-] Invitation to speak at BIO Virtual International Convention (390956)

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Cc: NIH Director Invitations <NIHDirectorInvitations@nih.gov>
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Sarah S. Arth, CAE
Vice President, Education
Biotechnology Innovation Organization

O - [b6]
M - [b6]

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Sent: Friday, May 29, 2020 9:33 AM
To: Sarah Arth [b6]; Phyllis Arthur [b6]
Cc: NIH Director Invitations <NIHDirectorInvitations@nih.gov>
Subject: [-EXTERNAL-] Invitation to speak at BIO Virtual International Convention (390956)
Importance: High

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With kind regards,

Patrice Allen-Gifford
Director
Executive Secretariat
National Institutes of Health
One Center Drive, B1-46
Bethesda, MD 20892
Tel: [b6]
Cell: [b6]

From: James C. Greenwood [b6]
Sent: Sunday, May 24, 2020 6:10 PM
To: Allen-Gifford, Patrice (NIH/OD) [E] [b6]
Cc: Sarah Arth [b6]; Twyman, Leslie (NIH/OD) [E] [b6]; NIH Director Invitations <NIHDirectorInvitations@nih.gov>; Phyllis Arthur [b6]
Subject: RE: [-EXTERNAL-] FW: For FC Decision: Invitation to speak at BIO Virtual International Convention (390956)

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To: James C. Greenwood [b6]
Cc: [b6] Twyman, Leslie (NIH/OD) [E]; [b6]; NIH Director Invitations
<NIHDirectorInvitations@nih.gov>
Subject: Invitation to speak at BIO Virtual International Convention

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Patrice Allen-Gifford
Director
Executive Secretariat
National Institutes of Health
Cell: [b6]

From: James C. Greenwood [b6]
Sent: Thursday, May 14, 2020 5:59 PM
To: Collins, Francis (NIH/OD) [E]; [b6]
Cc: sara.radcliffe.7 [b6]
Subject: Dr. Collins - Invitation to speak at BIO Virtual International Convention

Dear Francis,

I hope this email finds you well. Thanks for your grand leadership in this awful time. Given the current environment, we have taken our annual BIO International Convention to a digital format this year. COVID-19 will be at the forefront of the content that we are planning for the event and we would like to invite you to participate in our three-part plenary, *A Way Forward: Winning the War on COVID through Vaccines*. I have attached a formal invite with complete session details. The session will take place on Tuesday, June 9 from 2:30 PM – 3:30 PM ET virtually. We hope that you can join us.

I look forward to your response.

All the best,

From: Wolinetz, Carrie (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1C655040D47346C7B04D7BC11A403ECB-WOLINETZCD]
Sent: 5/29/2020 2:55:30 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
Subject: RE: [-EXTERNAL-] Invitation to speak at BIO Virtual International Convention (390956)

Seems pretty paltry to me, too. I think you should just say no. Alternatively, would Hilary Marston be an appropriate substitute? That way you could help them out with gender balance, take something off your plate, and maintain your "no manel" principle in one fell swoop...

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Friday, May 29, 2020 10:37 AM
To: Wolinetz, Carrie (NIH/OD) [E] [b6]
Cc: Tabak, Lawrence (NIH/OD) [E]
Subject: FW: [-EXTERNAL-] Invitation to speak at BIO Virtual International Convention (390956)

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To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Wood, Gretchen (NIH/OD) [E] [b6]
McManus, Ayanna (NIH/OD) [E] [b6]; Twyman, Leslie (NIH/OD) [E] [b6]
Coley, Gwendolyn (NIH/OD) [C]
Subject: FW: [-EXTERNAL-] Invitation to speak at BIO Virtual International Convention (390956)

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Cc: NIH Director Invitations <NIHDirectorInvitations@nih.gov>
Subject: RE: [-EXTERNAL-] Invitation to speak at BIO Virtual International Convention (390956)

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**Leveraging Platforms and Partnerships to Develop COVID-19 Vaccines in Record Time
Tuesday, June 9, 11:30 AM – 12:30 PM PT**

As numerous vaccines move through clinical development there are important issues that need to be addressed. How will companies and partners conduct global clinical trials? What are the key scientific issues that must be addressed to vaccinate millions of people worldwide? This panel will discuss the complex path to clinical trials, the impact of the evolving science on their

development and share their thoughts on how collaboration will bring life-saving vaccines to the world.

Moderator: Mark McClellan, MD, Director, Duke Margolis Center for Health Policy

Panelists:

- Gregory Glenn, MD, Chief Scientific Officer, Novavax
- Margaret Hamburg, MD, Foreign Secretary, National Academy of Medicine
- Peter Marks, MD, PhD, Director, Center for Biologics Evaluation and Research, United States Food and Drug Administration
- Gary Nabel, MD, PhD, Chief Scientific Officer, Sanofi (invited)
- Paul Stoffels, MD, Vice Chairman of the Executive Committee and Chief Scientific Officer, Johnson & Johnson

Sarah S. Arth, CAE
Vice President, Education
Biotechnology Innovation Organization

O - [b6]
M -

From: Allen-Gifford, Patrice (NIH/OD) [E] [b6]

Sent: Friday, May 29, 2020 9:33 AM

To: Sarah Arth [b6]; Phyllis Arthur [b6]

Cc: NIH Director Invitations <NIHDirectorInvitations@nih.gov>

Subject: [-EXTERNAL-] Invitation to speak at BIO Virtual International Convention (390956)

Importance: High

Good day,

I am writing to you in follow up to Mr. Greenwood's message to me earlier this week. Do you have any further information that we may share with Dr. Collins?

With kind regards,

Patrice Allen-Gifford
Director
Executive Secretariat
National Institutes of Health
One Center Drive, B1-46
Bethesda, MD 20892
Tel: [b6]
Cell: [b6]

From: James C. Greenwood [b6]

Sent: Sunday, May 24, 2020 6:10 PM

To: Allen-Gifford, Patrice (NIH/OD) [E] [b6]

Cc: Sarah Arth [b6]; Twyman, Leslie (NIH/OD) [E] [b6]; NIH Director Invitations <NIHDirectorInvitations@nih.gov>; Phyllis Arthur [b6]

Subject: RE: [-EXTERNAL-] FW: For FC Decision: Invitation to speak at BIO Virtual International Convention (390956)

Thank you, Patrice. I believe we have already managed to do this. My staff will respond to you.

From: Allen-Gifford, Patrice (NIH/OD) [E] [b6]
Sent: Sunday, May 24, 2020 5:56 PM
To: James C. Greenwood [b6]
Cc: [b6] Twyman, Leslie (NIH/OD) [E] [b6]; NIH Director Invitations
<NIHDirectorInvitations@nih.gov>
Subject: Invitation to speak at BIO Virtual International Convention

Dear Mr. Greenwood,

Dr. Collins received your invitation to speak as part of a three-part plenary at BIO's virtual convention on June 11 and has asked me to thank you for inviting him to participate in this important and timely discussion on Leveraging Platforms and Partnership to Develop COVID-19 vaccines. As you may know, Dr. Collins is very committed and devoting enormous time to just such a unique effort, known as ACTIV. He would like to contribute to the BIO panel discussion, however, he has also committed to inclusiveness and ensuring a level playing field in speaking opportunities; he issued a statement outlining his commitment last year. The panel proposed in your invitation letter does not reflect that diversity. May we ask if there is a possibility of creating a more inclusive panel of speakers? Thank you again for thinking of Dr. Collins and NIH.

Most respectfully,

Patrice Allen-Gifford
Director
Executive Secretariat
National Institutes of Health
Cell: [b6]

From: James C. Greenwood [b6]
Sent: Thursday, May 14, 2020 5:59 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: sara.radcliffe.7 [b6]
Subject: Dr. Collins - Invitation to speak at BIO Virtual International Convention

Dear Francis,

I hope this email finds you well. Thanks for your grand leadership in this awful time. Given the current environment, we have taken our annual BIO International Convention to a digital format this year. COVID-19 will be at the forefront of the content that we are planning for the event and we would like to invite you to participate in our three-part plenary, *A Way Forward: Winning the War on COVID through Vaccines*. I have attached a formal invite with complete session details. The session will take place on Tuesday, June 9 from 2:30 PM – 3:30 PM ET virtually. We hope that you can join us.

I look forward to your response.

All the best,

COLL0000017330-2443629

From: Wachtel, Jonathan [jwachtel@DELOITTE.com]
Sent: 5/29/2020 3:09:52 PM
To: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Garner, Carlos [b6]; Bascles, Lionel [b6]; Vincent, Mike [b6]; Payton, Manizhe (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [b6]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers, Betsy [b6]; Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshow, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshoj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Nayak, Seema (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Resnansky, Laura [b6]; Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Mensah, George (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Weinmann, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang]
CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Kublin MD, MPH, James [b6]; Ferguson, Sue [b6]; Kenny, Dermot [b6]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Criffield, Robin [b6]; Hamilton, Nancy [b6]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Minnich, Beth [b6]; Mueller-Reichenstein, Petra [b6]; Quadros, Nora [b6]; Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Hill, Zoe (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [marganderson@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Carluccio, Dana [b6]; Heaton, Penny [b6]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [b6]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveson, Nancy [b6]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative

Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [b6]; Jansen, Kathrin [b6]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [b6]

Subject: RE: ACTIV Clinical Trial Capacity Working Group - reporting meeting

Team-

As a follow-up to today's meeting/dashboard demo, please email me any additional feedback. I will ensure it gets back to Kevin and his team for incorporation into the tool.

Additionally, I am including the list of Networks which have submitted their site rosters to date. If you have any connections to missing Networks, feel free to send them a nudge or reminder to submit their roster so we can enrich our geotracking dashboard.

- ACTG
- ARLG
- PETAL
- ChiLDRen
- Clinical Trials in Organ Transplantation
- DILIN
- GpCRC
- GRADE
- HFN
- IDCRC
- iMALT
- LaRed
- MSC ARDS
- NASH CRN
- NEPTUNE
- PreCISE
- PTN
- TIN
- REPRIVE
- USDRN

Best,

Jonathan Wachtel
Deloitte Consulting LLP
Tel/Direct: [b6]
www.deloitte.com

-----Original Appointment-----

From: Tountas, Karen (FNIH) [T] [b6]

Sent: Friday, May 8, 2020 1:10 PM

To: Tountas, Karen (FNIH) [T]; Garner, Carlos; Bascles, Lionel; Vincent, Mike; Payton, Manizhe (NIH/NIAID) [E]; Cohen, Myron; Corey, Larry; Victoria Davey; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshov, James (NIH/NCI) [E];

Goff, David (NIH/NHLBI) [E]; Kurilla, Michael (NIH/NCATS) [E]; Nayak, Seema (NIH/NIAID) [E]; Qashu, Felicia (NIH/OD) [E]; Resnansky, Laura; Sizemore, Christine (NIH/FIC) [E]; Srinivasan, Badhri; Stein, Peter (FDA/CDER); Wachtel, Jonathan; Mensah, George (NIH/NHLBI) [E]; Weinmann, Gail (NIH/NHLBI) [E]

Cc: Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Kublin MD, MPH, James; Ferguson, Sue; Kenny, Dermot; Gonzalez, Nina; Criffield, Robin; Hamilton, Nancy; Melencio, Cheryl (FNIH) [T]; Minnich, Beth; Mueller-Reichenstein, Petra; Quadros, Nora; Katz, Rebecca (NIH/NCATS) [E]; Hill, Zoe (NIH/NHLBI) [C]; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Parker, Ashley (NIH/OD) [E]; Carluccio, Dana; Heaton, Penny; James, Stephanie (FNIH) [T]; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Tuveson, Nancy; Wholley, David (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John

Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting

When: Friday, May 29, 2020 9:00 AM-10:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: <https://fnih.zoom.us/j/95092792940?pwd=N0xKLzJodEd1ZjZFVmNibDVkQ0hXQT09>

Colleagues – Attaching the agenda for the call. Best, Karen

Dear Clinical Trial Capacity WG members, This will extend our full working group calls through the end of May. We'll assess the need for further meetings at the end of the month. Many thanks for your participation! Karen

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/29/2020 5:07:37 PM
To: Jim Neaton [b6]; Jens Lundgren [b6]; Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-roosenbey]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; LaVange, Lisa M [b6]; Karen Lynn Price [b6]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Carlos O Garner [b6]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]
CC: Chen, Helen Q. [qingchen@deloitte.com]; Demarcus [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Salathin, Carla [b6]

Subject: ACTIV-3 Writing Team and mAb Steering Committee Joint Meeting

Location: [b6]

Start: 6/5/2020 3:30:00 PM

End: 6/5/2020 4:30:00 PM

Show Time As: Tentative

Required Attendees: Jim Neaton; Jens Lundgren; Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Kozak, Marina (OS/ASPR/BARDA); Patterson, Amy (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Judy Currier; Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Lisa LaVange; Karen Lynn Price; Woodcock, Janet (FDA/CDER); Stein, Peter (FDA/CDER); Carlos O Garner; Bugin, Kevin; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Farley, John (FDA/CDER)

Optional Attendees: Chen, Helen Q.; Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Parker, Ashley (NIH/OD) [E]; Salathin, Carla

Stacey Adam is inviting you to a scheduled Zoom meeting.

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From: Prabha Fernandes [b6]
Sent: 5/29/2020 7:31:05 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskip]; [b6]
[b6] Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; [b6]
[b6] Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; [b6] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; [b6] Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; 'Rao, Srinivas' [b6]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; 'Tomas Cihlar' [b6] (USA) [b6]
CC: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; 'Hughes, Eric' [b6]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Cutillo, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c04c8f5063c34361bb7491f216f75adc-cutilloc]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; 'Desrosiers, Betsy' [b6]; 'Jansen, Kathrin' [b6]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4b79577e2aa8d1-jamesst]; 'Alvarez, Rosa Maria' [rosalvarez@deloitte.com]; 'Kim, Elizabeth' [elkim@deloitte.com]; 'Tolman, Brett' [btolman@deloitte.com];

'Wachtel, Jonathan' [jwachtel@deloitte.com]; 'Prabhavathi Fernandes' [b6] 'Diamond, Michael' [b6] 'Rose Li' [b6]; 'Dana Carluccio' [b6]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; 'Rodriguez, Robin D' [b6]; 'Dave Frankowski' [b6]; 'Baric, Toni C' [b6]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; 'Stratton, Benjamin' [bstratton@DELOITTE.com]

Subject: RE: ACTIV Preclinical working group (Tuesday meeting)

Attachments: GC376 A vet feline infectious peritonitis Anivive .pdf; GC376 JJ Virology 2015-Kim-feline coronavirusl - Copy.pdf

Hi Joe,

When we prioritize re-purposed drugs..

Should we include vet products. Anvive has announced it data on SARS CoV2.. they have been developing the compound for feline infectious peritonitis. Protease inhibitor.

Oral product.

Selectivity index is great..

Attached FYI in case you have not seen.

Regards,

Prabha

From: Menetski, Joseph (FNIH) [T] [b6]

Sent: Friday, May 29, 2020 3:25 PM

To: [b6] Hild, Sheri (NIH/OD) [E]

[b6]; Ottinger, Elizabeth (NIH/NCATS) [E] [b6]; Colvis, Christine (NIH/NCATS) [E] [b6]; Hewitt, Judith (NIH/NIAID) [E] [b6]; Deming, Damon (FDA/CDER) [b6]

[b6] Parker, Ashley (NIH/OD) [E]

[b6] Adams, Peter (OS/ASPR/BARDA)

[b6] Qashu, Felicia (NIH/OD) [E]

[b6] Tomas Cihlar [b6]

[b6] Adams, Peter (OS/ASPR/BARDA)

[b6] Qashu, Felicia (NIH/OD) [E]

[b6] Tomas Cihlar [b6]

[b6] Adams, Peter (OS/ASPR/BARDA)

[b6] Qashu, Felicia (NIH/OD) [E]

[b6] Tomas Cihlar [b6]

[b6] Adams, Peter (OS/ASPR/BARDA)

[b6] Qashu, Felicia (NIH/OD) [E]

[b6] Tomas Cihlar [b6]

[b6] Adams, Peter (OS/ASPR/BARDA)

[b6] Qashu, Felicia (NIH/OD) [E]

[b6] Tomas Cihlar [b6]

[b6] Adams, Peter (OS/ASPR/BARDA)

Brett <btolman@deloitte.com>; Wachtel, Jonathan <jwachtel@deloitte.com>; Prabhavathi Fernandes

[b6]; Diamond, Michael [b6]; Rose Li
[b6]; Dana Carluccio [b6]; Lagos, Enrique (NIH/NCATS) [E]
[b6]; Jonson, Samantha (NIH/NCATS) [E] [b6]; Burrus-Shaw, Cyndi
(NIH/OD) [E] [b6]; Rodriguez, Robin D [b6]; Dave Frankowski
[b6]; Baric, Toni C [b6]; Lowy, Douglas (NIH/NCI) [E]
[b6]; Florence, Clint (NIH/NIAID) [E] [b6]; Nancy Haigwood
[b6]; Stratton, Benjamin <bstratton@DELOITTE.com>

Subject: RE: ACTIV Preclinical working group (Tuesday meeting)

Dear Preclinical group and attendees,

Please find the minutes to our meeting on Wednesday. Let me know if you have any questions or concerns with these.

Thank you,

Joe

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T]

Sent: Tuesday, April 14, 2020 6:43 PM

To: [b6] Menetski, Joseph (FNIH) [T]; Hild, Sheri (NIH/OD) [E]; [b6]

[b6]

[b6] Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; [b6] Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; [b6] (USA)

Cc: Gadbois, Ellen (NIH/OD) [E]; Hughes, Eric; Gonzalez, Nina; Cutillo, Christine (NIH/NCATS) [E]; Simon, Dina (NIH/OD) [C]; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin

Subject: ACTIV Preclinical working group (Tuesday meeting)

When: Wednesday, May 27, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: [b6]

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting

[b6]

Meeting ID: [b6]

Password: [b6]

One tap mobile

[b6]

US (Germantown)
US (Chicago)

Dial by your location

b6

US (Germantown)

US (Chicago)

US (New York)

US (San Jose)

US (San Jose)

US (Tacoma)

US (Houston)

Meeting ID:

b6

Password:

b6

Find your local number:

b6

From: Freire, Maria (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8598D551D1D3455EAF14854C83F41D84-FREIREMC]
Sent: 5/29/2020 7:36:02 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Yes, I will send it to Nina.

From: Wholley, David (FNIH) [T] [b6]
Sent: Friday, May 29, 2020 3:33 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Adam, Stacey (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Gonzalez, Nina <ningonzalez@deloitte.com>; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

By copy to Nina Gonzalez, I am asking formally if that is OK. We are fine with that of course. Ashley and Maria are corresponding on a slide that might fit for #1.

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Friday, May 29, 2020 3:30 PM
To: Wholley, David (FNIH) [T] [b6]
Cc: Adam, Stacey (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Gonzalez, Nina <ningonzalez@deloitte.com>; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Hi David,

Sorry, had an e-mail crash and am just now seeing this – it's a good thing you didn't wait for me! The outline looks good, I'll wait for the Deloitte versions. I don't have a slide that fits #1. NHLBI (Amy Patterson) is working on things for me by COB on anticoagulants. If I need to harmonize, is Deloitte available this evening?

FC

From: Wholley, David (FNIH) [T] [b6]
Sent: Friday, May 29, 2020 1:59 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Adam, Stacey (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Gonzalez, Nina <ningonzalez@deloitte.com>; Parker, Ashley (NIH/OD) [E] [b6]
Subject: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Francis:

Here is the outline of the slides I am asking Deloitte to work to put together with key messages. I don't know if you or Ashley have a good version of slide #1; it is more of an OWS slide than an ACTIV one. I also don't know what input NHLBI wants to provide; I took the liberty of naming the anticoag MP as "ACTIV-4" in the interest of teaming up on a commonly branded strategy, hope that is OK. I am providing this to Deloitte now so they can get going on starting the slides, but please feel free to highlight maybe in red any wording you want changed or additions you would add in the meantime, and copy all on the reply.

- Maybe a diagram slide just reminding Moncef that OWS/Therapeutics and ACTIV are working together
- OWS/ACTIV Therapeutics has been taking a **portfolio** approach to addressing the dramatic health and economic challenges posed by the pandemic, with harmonized efforts that address both disease etiology and symptomology.
 - ACTIV Baricitinib (ACTT2, sponsored by NIAID) – in progress
 - ACTIV hiVIG (sponsored by NIAID) - in progress
 - ACTIV-1 – Inpatient Master Protocol of 3 host-targeted immune modulators (using CRO) – (Phase III) – ready to launch late June
 - ACTIV-2*– Neutralizing Monoclonal Antibodies Outpatient Master Protocol (using NIAID ACTG Network + CRO) – (Phase II/III) – projected launch June
 - ACTIV-3* – Neutralizing Monoclonal Antibodies Inpatient Master Protocol (NIAID INSIGHT Network + NHLBI PETAL Network + CRO) – (Phase II/III) – projected launch July
 - ACTIV-4 – Inpatient Master Protocols of 3+ Anticoagulant Therapies, and eventually, Anticoagulant+Immune Modulator Combinations (NHLBI-NINDS "Master" Network) – (Phase II/III) – projected launch late June
 - ACTIV-5 – De Novo Master Protocol Structure to test promising agents not effectively evaluated elsewhere (e.g., antivirals) – similar design to the mAb protocols, networks/sites/agents in discussions now – projected launch August (*if needed; i.e. if agents are not incorporated into mAb protocols*)
* current priority
[for this slide I think you can use the Agent Prioritization Snapshot slide (#12) from May 20 ACTIV EC call as a base
- Prioritization Process (v 2.0) for ACTIV : (slide 14 from May 20 EC deck)
- Results of First Agent Prioritization Reviews (slide 13 from May 20 deck)
[Key Criteria for Scoring (slide 15 from 5/20) can go to backup
- Prioritization and Protocol Design: Who is Involved – two-box slide containing names and affiliations of those involved in the Prioritization and MP Subgroups (quality folks!)
- ACTIV-1 Protocol for immunomodulators
 - Agent prioritization included input from COVID R&D Leadership Consortium planned testing of 8-9 repurposed agents funded by industry (2 highest priority agents switched to ACTIV-1)
 - 3 agents chosen are well-established anti-inflammatories with solid rationale for MOA in COVID-19, not already being adequately tested elsewhere
 - All 3 either have initial Phase II data or are currently running company-sponsored Phase II trials = high POS
 - Phase III master protocol design for ACTIV-1 includes aggressive efficacy and futility assessments to allow for early stopping at 25%, 50%, and 75% accrual, in order to quickly drop agents not showing efficacy (like a Phase II/III progression design, but design was faster for quicker launch)
 - Companies have agreed to share data + common control arm+ common endpoints + DSMB = efficiency and ability to compare results across arms (this does not happen if companies test separately)
 - Protocol is 80% complete
 - Substantial input from 25+ industry, academic, and government experts, including FDA clinical and stats
 - Statisticians include some of the best in the world for master protocol design: Lisa LaVange (UNC), Karen Price (Lilly), Michael Proschan (NIAID), Sandeep Menon (Pfizer)

- All three companies have written their sections of the protocols, which are being merged into the master design
 - Working with OWS/BARDA on choice of CRO to run the trial; revised cost estimate = \$60 million
- “ACTIV-4” Protocol for anticoagulants
 - Need bullets from NHLBI on this. Should emphasize similar themes (robust choice of agents through ACTIV process, powered by NHLBI/NINDS “network of networks” with rapid contracting and startup practices, protocol being drafted in parallel (ACTIV WG review), inclusion of vital natural history disease/treatment data, cost and justification, etc.)
- Maybe a final slide summarizing the budget asks? Should it include preclinical or just the clinical stuff? And perhaps NIH (Ashley) should draft that one given the sensitivity around the numbers?

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

b6

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Kara Carter [b6]
Sent: 5/29/2020 7:40:04 PM
To: Prabha Fernandes [b6]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; [b6]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; [b6]; [b6] Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; [b6] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; [b6] Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; 'Rao, Srinivas' [b6]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; 'Tomas Cihlar' [b6] (USA) [b6]
CC: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; 'Hughes, Eric' [b6]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Cutillo, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c04c8f5063c34361bb7491f216f75adc-cutilloc]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; 'Desrosiers, Betsy' [b6]; 'Jansen, Kathrin' [b6]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; 'Alvarez, Rosa Maria'

[rosalvarez@deloitte.com]; 'Kim, Elizabeth' [elkim@deloitte.com]; 'Tolman, Brett' [btolman@deloitte.com]; 'Wachtel, Jonathan' [jwachtel@deloitte.com]; 'Prabhavathi Fernandes' [b6] 'Diamond, Michael' [b6], 'Rose Li' [b6], 'Dana Carluccio' [b6], Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; 'Rodriguez, Robin D' [b6]; 'Dave Frankowski' [b6] 'Baric, Toni C' [b6]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; 'Stratton, Benjamin' [bstratton@DELOITTE.com]

Subject: RE: ACTIV Preclinical working group (Tuesday meeting)

Attachments: Ma et al 2020 BioRxiv Boceprevir GC-376 and calpain inhibitors II XII inhibit SARS-CoV-2 viral replication by targeting the viral main protease.pdf

Thanks Prabha. Here is the recent submission to BioRxiv from Ma et al with the data on SARS-CoV-2 of the compound.

Kara



Kara Carter, PhD
Executive Vice President Infectious Disease

[b6] (Mobile)

[b6]
www.evotec.com

From: Prabha Fernandes [b6]

Sent: Friday, May 29, 2020 3:31 PM

To: 'Menetski, Joseph (FNIH) [T]' [b6]

[b6] 'Hild, Sheri (NIH/OD) [E]' [b6]

[b6] Kara Carter [b6]

'Baric, Ralph' [b6] 'Ottinger, Elizabeth (NIH/NCATS) [E]' [b6] 'Colvis,

Christine (NIH/NCATS) [E]' [b6]; 'Hewitt, Judith (NIH/NIAID) [E]' [b6] 'Deming,

Damon (FDA/CDER)' [b6]

[b6] 'Parker, Ashley (NIH/OD) [E]' [b6]

'Adams, Peter (OS/ASPR/BARDA)' [b6]; 'Rao, Srinivas' [b6] 'Qashu, Felicia

(NIH/OD) [E]' [b6]; 'Tomas Cihlar' [b6]

[b6] (USA)' [b6]

Cc: 'Gadbois, Ellen (NIH/OD) [E]' [b6] 'Hughes, Eric' [b6] 'Gonzalez, Nina'

<ningonzalez@deloitte.com>; 'Cutillo, Christine (NIH/NCATS) [E]' [b6]; 'Simon, Dina (NIH/OD) [C]'

[b6] 'Wholley, David (FNIH) [T]' [b6] 'Austin, Christopher (NIH/NCATS) [E]'

[b6] 'Melencio, Cheryl (FNIH) [T]' [b6] 'Colvis, Christine (NIH/NCATS) [E]'

[b6] 'Desrosiers, Betsy' [b6] 'Jansen, Kathrin'

[b6]; 'Kurilla, Michael (NIH/NCATS) [E]' [b6] 'Lowy, Douglas (NCI)'

[b6]; 'Read, Sarah (NIH/NIAID) [E] [b6]; 'Tountas, Karen (FNIH) [T] [b6]; 'Santos, Michael (FNIH) [T] [b6]; 'Adam, Stacey (FNIH) [T] [b6]; 'James, Stephanie (FNIH) [T] [b6]; 'Alvarez, Rosa Maria' <rosalvarez@deloitte.com>; 'Kim, Elizabeth' <elkim@deloitte.com>; 'Tolman, Brett' <btolman@deloitte.com>; 'Wachtel, Jonathan' <jwachtel@deloitte.com>; 'Prabhavathi Fernandes' [b6]; 'Diamond, Michael' [b6]; 'Rose Li' [b6]; 'Dana Carluccio' [b6]; 'Lagos, Enrique (NIH/NCATS) [E] [b6]; 'Jonson, Samantha (NIH/NCATS) [E] [b6]; 'Burrus-Shaw, Cyndi (NIH/OD) [E] [b6]; 'Rodriguez, Robin D' [b6]; 'Dave Frankowski' [b6]; 'Baric, Toni C' [b6]; 'Lowy, Douglas (NIH/NCI) [E] [b6]; 'Florence, Clint (NIH/NIAID) [E] [b6]; 'Nancy Haigwood' [b6]; 'Stratton, Benjamin' <bstratton@DELOITTE.com>

Subject: RE: ACTIV Preclinical working group (Tuesday meeting)

[EXTERNAL]

Hi Joe,

When we prioritize re-purposed drugs..

Should we include vet products. Anvive has announced it data on SARS CoV2.. they have been developing the compound for feline infectious peritonitis. Protease inhibitor.

Oral product.

Selectivity index is great..

Attached FYI in case you have not seen.

Regards,

Prabha

From: Menetski, Joseph (FNIH) [T] [b6]

Sent: Friday, May 29, 2020 3:25 PM

To: [b6] Hild, Sheri (NIH/OD) [E] [b6]; [b6] Baric, Ralph [b6] Ottinger, Elizabeth (NIH/NCATS) [E] [b6]; Colvis, Christine (NIH/NCATS) [E] [b6] Hewitt, Judith (NIH/NIAID) [E] [b6] Deming, Damon (FDA/CDER) [b6] [b6] Parker, Ashley (NIH/OD) [E] [b6] Adams, Peter (OS/ASPR/BARDA) [b6] Rao, Srinivas [b6] Qashu, Felicia (NIH/OD) [E] [b6] Tomas Cihlar [b6] (USA) [b6] **Cc:** Gadbois, Ellen (NIH/OD) [E] [b6] Hughes, Eric [b6] Gonzalez, Nina <ningonzalez@deloitte.com>; Cutillo, Christine (NIH/NCATS) [E] [b6] Simon, Dina (NIH/OD) [C] [b6] Wholley, David (FNIH) [T] [b6] Austin, Christopher (NIH/NCATS) [E] [b6] Melencio, Cheryl (FNIH) [T] [b6] Colvis, Christine (NIH/NCATS) [E] [b6] Desrosiers, Betsy [b6] Jansen, Kathrin [b6] Kurilla, Michael (NIH/NCATS) [E] [b6] Lowy, Douglas (NCI) [b6] Read, Sarah (NIH/NIAID) [E] [b6] Tountas, Karen (FNIH) [T] [b6] Santos, Michael (FNIH) [T] [b6] Adam, Stacey (FNIH) [T] [b6] James, Stephanie (FNIH) [T] <[b6] Alvarez, Rosa Maria <rosalvarez@deloitte.com>; Kim, Elizabeth <elkim@deloitte.com>; Tolman, Brett <btolman@deloitte.com>; Wachtel, Jonathan <jwachtel@deloitte.com>; Prabhavathi Fernandes [b6] Diamond, Michael [b6] Rose Li [b6] Dana Carluccio [b6]; Lagos, Enrique (NIH/NCATS) [E]

[b6]; Jonson, Samantha (NIH/NCATS) [E] [b6]; Burrus-Shaw, Cyndi (NIH/OD) [E] [b6]; Rodriguez, Robin D [b6] Dave Frankowski [b6] Baric, Toni C [b6] Lowy, Douglas (NIH/NCI) [E] [b6] Florence, Clint (NIH/NIAID) [E] [b6]; Nancy Haigwood [b6] Stratton, Benjamin <bstratton@DELOITTE.com>

Subject: RE: ACTIV Preclinical working group (Tuesday meeting)

Dear Preclinical group and attendees,

Please find the minutes to our meeting on Wednesday. Let me know if you have any questions or concerns with these.

Thank you,

Joe

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T]

Sent: Tuesday, April 14, 2020 6:43 PM

To: [b6] Menetski, Joseph (FNIH) [T]; Hild, Sheri (NIH/OD) [E]; [b6]

[b6]

[b6]

[b6] Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; [b6] Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; [b6] (USA)

Cc: Gadbois, Ellen (NIH/OD) [E]; Hughes, Eric; Gonzalez, Nina; Cutillo, Christine (NIH/NCATS) [E]; Simon, Dina (NIH/OD) [C]; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin

Subject: ACTIV Preclinical working group (Tuesday meeting)

When: Wednesday, May 27, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where [b6]

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting

[b6]

Meeting ID: [b6]

Password: [b6]

One tap mobile

[b6]

US (Germantown)

US (Chicago)

Dial by your location

[b6]

US (Germantown)

US (Chicago)

b6

US (New York)
US (San Jose)
US (San Jose)
US (Tacoma)
US (Houston)

Meeting ID: **b6**

Password: **b6**

Find your local number: **b6**

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If received in error, please notify us immediately by reply email and then delete this email and any attachments from your system. Thank you!

Please find our information on data protection [here](#).

From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 5/29/2020 7:40:20 PM
To: [b6] Hild, Sheri (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; [b6]
[b6] Baric, Ralph
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
[b6] Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
[b6] Parker, Ashley (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras];
[b6] Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [b6]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [b6] (USA) [b6]
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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c04c8f5063c34361bb7491f216f75adc-cutilloc]; Simon, Dina (NIH/OD) [C]
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Wholley, David (FNIH) [T]
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T]
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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T]
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T]
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T]
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T]
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4b79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Kim, Elizabeth [elkim@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Wachtel,

Jonathan [jwachtel@deloitte.com]; Prabhavathi Fernandes [b6]; Diamond, Michael [b6]; Rose Li [b6]; Dana Carluccio [b6]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [b6]; Dave Frankowski [david.frankowski@roseliassociates.com]; Baric, Toni C [b6]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin [bstratton@DELOITTE.com]

Subject: RE: ACTIV Preclinical working group (Tuesday meeting)

Attachments: 2020-05-27_Preclinical_WG_Summary_D1.docx

This time with the attachment.

Subject: RE: ACTIV Preclinical working group (Tuesday meeting)

Dear Preclinical group and attendees,

Please find the minutes to our meeting on Wednesday. Let me know if you have any questions or concerns with these.

Thank you,

Joe

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T]

Sent: Tuesday, April 14, 2020 6:43 PM

To: [b6]; Menetski, Joseph (FNIH) [T]; Hild, Sheri (NIH/OD) [E]; [b6]

b6

[b6] Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; [b6] Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; [b6] (USA)

Cc: Gadbois, Ellen (NIH/OD) [E]; Hughes, Eric; Gonzalez, Nina; Cutillo, Christine (NIH/NCATS) [E]; Simon, Dina (NIH/OD) [C]; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin

Subject: ACTIV Preclinical working group (Tuesday meeting)

APAR0000004843-2444033

When: Wednesday, May 27, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: b6

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting

b6

Meeting ID: b6

Password: b6

One tap mobile

b6	US (Germantown)
	US (Chicago)

Dial by your location

b6	US (Germantown)
	US (Chicago)
	US (New York)
	US (San Jose)
	US (San Jose)
	US (Tacoma)
	US (Houston)

Meeting ID: b6

Password: b6

Find your local number: b6

From: Prabha Fernandes [b6]
Sent: 5/29/2020 7:42:01 PM
To: 'Kara Carter' [b6]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; [b6]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; [b6] [b6]; Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; [b6] [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; [b6] [b6]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; 'Rao, Srinivas' [b6]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; 'Tomas Cihlar' [b6] (USA) [b6]
CC: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; 'Hughes, Eric' [b6]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Cutillo, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c04c8f5063c34361bb7491f216f75adc-cutilloc]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; 'Desrosiers, Betsy' [b6] [b6]; 'Jansen, Kathrin' [b6] [b6]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; 'Alvarez, Rosa Maria'

[rosalvarez@deloitte.com]; 'Kim, Elizabeth' [elkim@deloitte.com]; 'Tolman, Brett' [btolman@deloitte.com]; 'Wachtel, Jonathan' [jwachtel@deloitte.com]; 'Prabhavathi Fernandes' [b6]; 'Diamond, Michael' [b6]; 'Rose Li' [b6]; 'Dana Carluccio' [b6]; 'Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; 'Rodriguez, Robin D' [b6]; 'Dave Frankowski' [b6]; 'Baric, Toni C' [b6]; 'Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; 'Stratton, Benjamin' [bstratton@DELOITTE.com]

Subject: RE: ACTIV Preclinical working group (Tuesday meeting)

Thx much Kara!

I just heard that it is being made and sold black market in China.

From: Kara Carter [b6]

Sent: Friday, May 29, 2020 3:40 PM

To: Prabha Fernandes [b6]; 'Menetski, Joseph (FNIH) [T]' [b6]

[b6]; 'Hild, Sheri (NIH/OD) [E]' [b6]

[b6]

[b6]; 'Baric, Ralph' [b6]; 'Ottinger, Elizabeth (NIH/NCATS) [E]' [b6]

[b6]; 'Colvis, Christine (NIH/NCATS) [E]' [b6]; 'Hewitt, Judith (NIH/NIAID)

[E]' [b6]; 'Deming, Damon (FDA/CDER)' [b6]

[b6]; 'Parker, Ashley (NIH/OD) [E]' [b6]

[b6]; 'Adams, Peter (OS/ASPR/BARDA)' [b6]; 'Rao, Srinivas'

[b6]; 'Qashu, Felicia (NIH/OD) [E]' [b6]; 'Tomas Cihlar'

[b6] (USA)' [b6]

Cc: 'Gadbois, Ellen (NIH/OD) [E]' [b6]; 'Hughes, Eric' [b6]; 'Gonzalez, Nina'

<ningonzalez@deloitte.com>; 'Cutillo, Christine (NIH/NCATS) [E]' [b6]; 'Simon, Dina (NIH/OD) [C]'

[b6]; 'Wholley, David (FNIH) [T]' [b6]; 'Austin, Christopher (NIH/NCATS) [E]'

[b6]; 'Melencio, Cheryl (FNIH) [T]' [b6]; 'Colvis, Christine (NIH/NCATS) [E]'

[b6]; 'Desrosiers, Betsy' [b6]; 'Jansen, Kathrin'

[b6]; 'Kurilla, Michael (NIH/NCATS) [E]' [b6]; 'Lowy, Douglas (NCI)'

[b6]; 'Read, Sarah (NIH/NIAID) [E]' [b6]; 'Tountas, Karen (FNIH) [T]'

[b6]; 'Santos, Michael (FNIH) [T]' [b6]; 'Adam, Stacey (FNIH) [T]' [b6]

'James, Stephanie (FNIH) [T]' [b6]; 'Alvarez, Rosa Maria' <rosalvarez@deloitte.com>; 'Kim, Elizabeth'

<elkim@deloitte.com>; 'Tolman, Brett' <btolman@deloitte.com>; 'Wachtel, Jonathan' <jwachtel@deloitte.com>;

'Prabhavathi Fernandes' [b6]; 'Diamond, Michael' [b6]; 'Rose Li'

[b6]; 'Dana Carluccio' [b6]; 'Lagos, Enrique (NIH/NCATS)

[E]' [b6]; 'Jonson, Samantha (NIH/NCATS) [E]' [b6]; 'Burrus-Shaw, Cyndi

(NIH/OD) [E]' [b6]; 'Rodriguez, Robin D' [b6]; 'Dave Frankowski'

[b6]; 'Baric, Toni C' [b6]; 'Lowy, Douglas (NIH/NCI)

[E]' [b6]; 'Florence, Clint (NIH/NIAID) [E]' [b6]; 'Nancy Haigwood'

[b6]; 'Stratton, Benjamin' <bstratton@DELOITTE.com>

Subject: RE: ACTIV Preclinical working group (Tuesday meeting)

Thanks Prabha. Here is the recent submission to BioRxiv from Ma et al with the data on SARS-CoV-2 of the compound.

Kara



Kara Carter, PhD

Executive Vice President Infectious Disease

[REDACTED] (Mobile)

[REDACTED]
www.evotec.com

From: Prabha Fernandes [REDACTED]

[REDACTED]

Sent: Friday, May 29, 2020 3:31 PM

To: 'Menetski, Joseph (FNIH) [T]' [REDACTED]

[REDACTED]

[REDACTED]

'Hild, Sheri (NIH/OD) [E]' [REDACTED]

[REDACTED]

[REDACTED]

Kara Carter [REDACTED]

[REDACTED]

'Baric, Ralph [REDACTED]

[REDACTED]

'; 'Ottinger, Elizabeth (NIH/NCATS [E]' [REDACTED]

[REDACTED]

'; 'Colvis,

Christine (NIH/NCATS) [E]' [REDACTED]

[REDACTED]

'; 'Hewitt, Judith (NIH/NIAID) [E]' [REDACTED]

[REDACTED]

'Deming,

Damon (FDA/CDER)' [REDACTED]

[REDACTED]

[REDACTED]

'Parker, Ashley (NIH/OD) [E]' [REDACTED]

[REDACTED]

'Adams, Peter (OS/ASPR/BARDA)' [REDACTED]

[REDACTED]

> 'Rao, Srinivas' <

[REDACTED]

'Qashu, Felicia

(NIH/OD) [E]' [REDACTED]

[REDACTED]

'Tomas Cihlar' [REDACTED]

[REDACTED]

'Pitt, Margaret L CIV USARMY

[REDACTED]

USA)' [REDACTED]

[REDACTED]

Cc: 'Gadbois, Ellen (NIH/OD) [E]' [REDACTED]

[REDACTED]

'; 'Hughes, Eric' [REDACTED]

[REDACTED]

'; 'Gonzalez, Nina'

<ningonzalez@deloitte.com>; 'Cutillo, Christine (NIH/NCATS) [E]' [REDACTED]

[REDACTED]

'; 'Simon, Dina (NIH/OD) [C]'

[REDACTED]

'Wholley, David (FNIH) [T]' [REDACTED]

[REDACTED]

'; 'Austin, Christopher (NIH/NCATS) [E]'

[REDACTED]

'Melencio, Cheryl (FNIH) [T]' [REDACTED]

[REDACTED]

'; 'Colvis, Christine (NIH/NCATS) [E]'

[REDACTED]

'Desrosiers, Betsy' [REDACTED]

[REDACTED]

'; 'Jansen, Kathrin'

[REDACTED]

'Kurilla, Michael (NIH/NCATS) [E]' [REDACTED]

[REDACTED]

> 'Lowy, Douglas (NCI)'

[REDACTED]

'Read, Sarah (NIH/NIAID) [E]' [REDACTED]

[REDACTED]

'Tountas, Karen (FNIH) [T]'

[REDACTED]

'Santos, Michael (FNIH) [T]' [REDACTED]

[REDACTED]

'Adam, Stacey (FNIH) [T]' <

[REDACTED]

'James, Stephanie (FNIH) [T]' [REDACTED]

[REDACTED]

'Alvarez, Rosa Maria' <rosalvarez@deloitte.com>; 'Kim, Elizabeth'

[REDACTED]

'Tolman, Brett' <btolman@deloitte.com>; 'Wachtel, Jonathan' <jwachtel@deloitte.com>;

'Prabhavathi Fernandes' [REDACTED]

[REDACTED]

'Diamond, Michael' [REDACTED]

[REDACTED]

'Rose Li'

[REDACTED]

> 'Dana Carluccio' [REDACTED]

[REDACTED]

> 'Lagos, Enrique (NIH/NCATS)

[E]' [REDACTED]

[REDACTED]

> 'Jonson, Samantha (NIH/NCATS) [E]' [REDACTED]

[REDACTED]

> 'Burrus-Shaw, Cyndi

(NIH/OD) [E]' [REDACTED]

[REDACTED]

> 'Rodriguez, Robin D' [REDACTED]

[REDACTED]

'Dave Frankowski'

[REDACTED]

'Baric, Toni C' [REDACTED]

[REDACTED]

'Lowy, Douglas (NIH/NCI)

[E]' [REDACTED]

[REDACTED]

'Florence, Clint (NIH/NIAID) [E]' [REDACTED]

[REDACTED]

'; 'Nancy Haigwood'

[REDACTED]

'Stratton, Benjamin' <bstratton@DELOITTE.com>

Subject: RE: ACTIV Preclinical working group (Tuesday meeting)

[EXTERNAL]

Hi Joe,

When we prioritize re-purposed drugs..

APAR0000004839

Should we include vet products. Anvive has announced it data on SARS CoV2.. they have been developing the compound for feline infectious peritonitis. Protease inhibitor.

Oral product.

Selectivity index is great..

Attached FYI in case you have not seen.

Regards,
Prabha

From: Menetski, Joseph (FNIH) [T] b6

Sent: Friday, May 29, 2020 3:25 PM

To: b6 Hild, Sheri (NIH/OD) [E]
b6
b6 Baric, Ralph b6 Ottinger,
Elizabeth (NIH/NCATS) [E] b6 Colvis, Christine (NIH/NCATS) [E] b6
Hewitt, Judith (NIH/NIAID) [E] b6 Deming, Damon (FDA/CDER) b6
b6 Parker, Ashley (NIH/OD) [E]
b6 Adams, Peter (OS/ASPR/BARDA)
b6 Rao, Sriniva b6 Qashu, Felicia (NIH/OD) [E]
b6 Tomas Cihlar b6
(USA) b6
Cc: Gadbois, Ellen (NIH/OD) [E] b6 Hughes, Eric b6 Gonzalez, Nina
<ningonzalez@deloitte.com>; Cutillo, Christine (NIH/NCATS) [E] b6 Simon, Dina (NIH/OD) [C]
b6 Wholley, David (FNIH) [T] b6 Austin, Christopher (NIH/NCATS) [E]
b6 Melencio, Cheryl (FNIH) [T] b6 Colvis, Christine (NIH/NCATS) [E]
b6 Desrosiers, Betsy b6 Jansen, Kathrin
b6 Kurilla, Michael (NIH/NCATS) [E] b6 Lowy, Douglas (NCI)
b6 Read, Sarah (NIH/NIAID) [E] b6 Tountas, Karen (FNIH) [T] b6
Santos, Michael (FNIH) [T] b6 Adam, Stacey (FNIH) [T] b6 James, Stephanie (FNIH)
[T] b6 Alvarez, Rosa Maria <rosalvarez@deloitte.com>; Kim, Elizabeth <elkim@deloitte.com>; Tolman,
Brett <btolman@deloitte.com>; Wachtel, Jonathan <jwachtel@deloitte.com>; Prabhavathi Fernandes
b6 Diamond, Michael b6 Rose Li
b6 Dana Carluccio b6 Lagos, Enrique (NIH/NCATS) [E]
b6 Jonson, Samantha (NIH/NCATS) [E] b6 Burrus-Shaw, Cyndi
(NIH/OD) [E] b6 Rodriguez, Robin D b6 Dave Frankowski
b6 Baric, Toni C b6 Lowy, Douglas (NIH/NCI) [E]
b6 Florence, Clint (NIH/NIAID) [E] b6 Nancy Haigwood
Stratton, Benjamin <bstratton@DELOITTE.com>

Subject: RE: ACTIV Preclinical working group (Tuesday meeting)

Dear Preclinical group and attendees,

Please find the minutes to our meeting on Wednesday. Let me know if you have any questions or concerns with these.

Thank you,

Joe

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T]

Sent: Tuesday, April 14, 2020 6:43 PM

APAR0000004839

To: [b6] Menetski, Joseph (FNIH) [T]; Hild, Sheri (NIH/OD) [E]; [b6]
[b6]
[b6] Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; [b6] Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; [b6] (USA)
Cc: Gadbois, Ellen (NIH/OD) [E]; Hughes, Eric; Gonzalez, Nina; Cutillo, Christine (NIH/NCATS) [E]; Simon, Dina (NIH/OD) [C]; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin
Subject: ACTIV Preclinical working group (Tuesday meeting)
When: Wednesday, May 27, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: [b6]

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting

[b6]

Meeting ID: [b6]

Password: [b6]

One tap mobile

[b6] US (Germantown)
US (Chicago)

Dial by your location

[b6] US (Germantown)
US (Chicago)
US (New York)
US (San Jose)
US (San Jose)
US (Tacoma)
US (Houston)

Meeting ID: [b6]

Password: [b6]

Find your local number [b6]

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If received in error, please notify us immediately by reply email and then delete this email and any attachments from your system. Thank you!

Please find our information on data protection [here](#).

APAR0000004839

From: Gonzalez, Nina [ningonzalez@deloitte.com]
Sent: 5/29/2020 7:45:38 PM
To: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Elsaid, Olivia [oelsaid@deloitte.com]; Stratton, Benjamin [bstratton@DELOITTE.com]
Subject: RE: Key messages immunomodulators for slides for Moncef meeting tomorrow 5/30

All –

Deloitte is available for any slide harmonization this evening – just let Olivia and I know what you need.

Thanks,

Nina

From: Freire, Maria (FNIH) [T] [b6]
Sent: Friday, May 29, 2020 3:36 PM
To: Wholley, David (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]
Cc: Adam, Stacey (FNIH) [T] [b6]; Gonzalez, Nina <ningonzalez@deloitte.com>; Parker, Ashley (NIH/OD) [E] [b6]
Subject: [EXT] RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Yes, I will send it to Nina.

From: Wholley, David (FNIH) [T] [b6]
Sent: Friday, May 29, 2020 3:33 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Adam, Stacey (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Gonzalez, Nina <ningonzalez@deloitte.com>; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

By copy to Nina Gonzalez, I am asking formally if that is OK. We are fine with that of course. Ashley and Maria are corresponding on a slide that might fit for #1.

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Friday, May 29, 2020 3:30 PM
To: Wholley, David (FNIH) [T] [b6]
Cc: Adam, Stacey (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Gonzalez, Nina <ningonzalez@deloitte.com>; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Hi David,

Sorry, had an e-mail crash and am just now seeing this – it’s a good thing you didn’t wait for me! The outline looks good, I’ll wait for the Deloitte versions. I don’t have a slide that fits #1. NHLBI (Amy Patterson) is working on things for me by COB on anticoagulants. If I need to harmonize, is Deloitte available this evening?

FC

From: Wholley, David (FNIH) [T] [b6]
Sent: Friday, May 29, 2020 1:59 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Adam, Stacey (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Gonzalez, Nina <ningonzalez@deloitte.com>; Parker, Ashley (NIH/OD) [E] [b6]
Subject: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Francis:

Here is the outline of the slides I am asking Deloitte to work to put together with key messages. I don’t know if you or Ashley have a good version of slide #1; it is more of an OWS slide than an ACTIV one. I also don’t know what input NHLBI wants to provide; I took the liberty of naming the anticoag MP as “ACTIV-4” in the interest of teaming up on a commonly branded strategy, hope that is OK. I am providing this to Deloitte now so they can get going on starting the slides, but please feel free to highlight maybe in red any wording you want changed or additions you would add in the meantime, and copy all on the reply.

- Maybe a diagram slide just reminding Moncef that OWS/Therapeutics and ACTIV are working together
 - OWS/ACTIV Therapeutics has been taking a **portfolio** approach to addressing the dramatic health and economic challenges posed by the pandemic, with harmonized efforts that address both disease etiology and symptomology.
 - ACTIV Baricitinib (ACTT2, sponsored by NIAID) – in progress
 - ACTIV hiVIG (sponsored by NIAID) - in progress
 - ACTIV-1 – Inpatient Master Protocol of 3 host-targeted immune modulators (using CRO) – (Phase III) – ready to launch late June
 - ACTIV-2*– Neutralizing Monoclonal Antibodies Outpatient Master Protocol (using NIAID ACTG Network + CRO) – (Phase II/III) – projected launch June
 - ACTIV-3* – Neutralizing Monoclonal Antibodies Inpatient Master Protocol (NIAID INSIGHT Network + NHLBI PETAL Network + CRO) – (Phase II/III) – projected launch July
 - ACTIV-4 – Inpatient Master Protocols of 3+ Anticoagulant Therapies, and eventually, Anticoagulant+Immune Modulator Combinations (NHLBI-NINDS “Master” Network) – (Phase II/III) – projected launch late June
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v.E.1

APAR0000001343

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 5/29/2020 9:58:59 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30
Attachments: Responses to Qs re AC Clinical Trial Strategy 052920 final fsc.docx

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From: Stacey Adam (Basecamp) b6
Sent: 5/29/2020 10:46:17 PM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadbois@] [Redacted]
Subject: Stacey A. added you to a team in Basecamp (FNIH Research Partnerships)



Stacey Adam added you to ACTIV - Clinical Trial Capacity WG in Basecamp

[Join Stacey in Basecamp](#)

If you have any questions, just email Stacey or reply to this message.

Here's what's happened so far...

30 other people are on this team from our team

Badhri Srinivasan, Carlos Garner, Cheryl Melencio, Christine Sizemore, David Goff, Deanna Garner, Elizabeth Desrosiers, Felicia Qashu, Gail Weinmann, George Mensah, James Dickens, Janet Woodcock, Jim Doroshov, Jonathan Wachtel, Karen Tountas, Kevin Bugin, Kevin Footer, Larry Corey, Laura Resnansky, Lionel Bascles, Lynn Marks, Michael Vincent, Mike Kurilla, Molly Klote, Myron Cohen, Payton Manizhe, Peter Stein, Seema Nayak, Vicky Davey, and Victoria Davey.

Docs & Files were added for reference

Clinical_Trial_Capacity_Working_Group_Meeting_12_Final.pdf
Clinical_Trial_Capacity_Working_Group_Meeting_10_Final.pdf
Clinical_Trial_Capacity_Working_Group_Meeting_9_Final.pdf
Copy of Innovations Matrix 14May.xlsx
Clinical_Trial_Capacity_Working_Group_Meeting_8_Summary_Final.pdf
03 ACTIV Clinical Trial CRO-SMO Survey #1 May 2020.docx
02 ACTIV Clinical Trial SITE Survey #1 APRIL 2020.docx
01 ACTIV Clinical Trial NETWORK Survey #1 APRIL 2020.docx
Network Inventory Master Spreadsheet 05122020.xlsx
Clinical_Trial_Capacity_Working_Group_Meeting_7_Summary_Final.pdf
+ 42 more items...

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GADB0000003780

a12b1ccd31891747a7e2a4df

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Subject: Stacey A. added you to a team in Basecamp (FNIH Research Partnerships)



Stacey Adam added you to ACTIV - Therapeutics Clinical WG in Basecamp

[Join Stacey in Basecamp](#)

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Amanda Peppercorn, Ashley Parker, Carlos Garner, Cheryl Melencio, David Goff, Deanna Garner, Elizabeth Higgs, Elizabeth Kim, Elliott Levy, Eric Hughes, Felicia Qashu, Helen Q. Chen, Janet Woodcock, Joan Butterson, John Mellors, Judy Currier, Keith Gottesdiener, Kevin Bugin, Lisa LaVange, Lora Reineck, Lynn Marks, Mary Biggs, Michael Proschan, Mike Poole, Naimish Patel, Neil Aggarwal, Peter Stein, R. Angelo De Claro, Ruxandra Draghia-Akli, Sam Bozzette, Sandeep Menon, Sarah Wynne Read, Sylva Collins, Tim Buchman, and Timothy Burgess.

Docs & Files were added for reference

ACTIV_Therapeutics-Clinical_ACTIV TX-Clinical Neutralizing mAb Master Protocol Steering Committee with PETAL Network Leads_20May2020_Key Takeaways.pdf
ACTIV_Therapeutics-Clinical_AP Sub-Group Meeting 14May2020_Key Takeaways.pdf
ACTIV Therapeutics Clinical MP Sub Group 15May2020_Meeting Agenda.pdf
2020-05-14_TX-Clinical_WG_Agent_Prioritization_Committee_Meeting Summary.pdf
2020-05-14_TX-Clinical_WG_Meeting_Summary.pdf
ACTIV_Therapeutics-Clinical_MP Sub-Group Meeting 15May2020_Key Takeaways.pdf
ACTIV_Therapeutics-Clinical_AP Sub-Group Meeting 12May2020 Key Takeaways.pdf
ACTIV Therapeutics-Clinical_MP Subgroup_13May2020 Meeting Guide.pdf
ACTIV Therapeutics-Clinical Full Working Group_14May2020 Meeting Guide.pdf
2020-05-07_TX-Clinical_WG_Meeting_Summary.pdf
+ 127 more items...

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6e75feb35dea7cf161d98901

From: Freire, Maria (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8598D551D1D3455EAF14854C83F41D84-FREIREMC]
Sent: 5/29/2020 10:49:02 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: Re: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30



On May 29, 2020, at 6:44 PM, Collins, Francis (NIH/OD) [E] [b6] wrote:

Yes, she is waiting to see the draft ppts and will advise on the strategy then.

Sent from my iPhone

On May 29, 2020, at 6:06 PM, Freire, Maria (FNIH) [T] [b6] wrote:

Francis - have you had a chance to chat with Janet to coordinate messages? She is critical - in her low-key way, she is able to carry a huge part of the load. Moncef knows she has a rock-solid reputation with industry folks. And, of course, she was the one who asked for the money. M.

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Sent: 5/30/2020 12:33:01 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
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Sent: Friday, May 29, 2020 8:32 PM
To: Wholley, David (FNIH) [T] [b6]
Cc: Adam, Stacey (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Gonzalez, Nina <ningonzalez@deloitte.com>; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Hoping these are coming to me soon, as I may want to do some editing -- and then I wanted to run them past Janet tonight.

FC

From: Wholley, David (FNIH) [T] [b6]
Sent: Friday, May 29, 2020 7:41 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Adam, Stacey (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Gonzalez, Nina <ningonzalez@deloitte.com>; Parker, Ashley (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]
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Have seen and offered a few changes to the complete slide deck. They should be coming back to you as soon as Deloitte makes the changes.

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Sent: 5/30/2020 12:33:03 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Hi Francis,

Back to you in moments.

Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: [b6] Mobile: [b6]

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Sent: Friday, May 29, 2020 8:32 PM
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Subject: RE: Key messages immunomodulators for slides for Moncef meeting tomorrow 5/30
Attachments: ACTIV Clinical Trials Discussion 20200529 v6.pptx

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Nina Gonzalez

Deloitte Consulting LLP

Tel/Direct: +1 202 748 6535

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Attachments: ACTIV Therapeutics_053020.pptx

Hi all,

Thanks, this is an excellent set, though to keep the discussions with Moncef concise, I've moved some of the slides to the Appendix. See current version. I will send this to Janet now too.

One question: when the immunomodulator slide 7 says this:

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What does that mean? Phase II trials for what application?

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b6

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COLL0000009631

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 5/30/2020 1:01:41 AM
To: Gonzalez, Nina [ningonzalez@deloitte.com]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Elsaid, Olivia [oelsaid@deloitte.com]
Subject: RE: Key messages immunomodulators for slides for Moncef meeting tomorrow 5/30
Attachments: ACTIV Therapeutics_053020.pptx

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Cc: Adam, Stacey (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Elsaid, Olivia <oelsaid@deloitte.com>
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Thank you,

Nina

Nina Gonzalez
Deloitte Consulting LLP
Tel/Direct: +1 202 748 6535

COLL0000020603

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Subject: [EXT] RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

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Sent: 5/30/2020 1:17:20 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Elsaid, Olivia [oelsaid@deloitte.com]
Subject: RE: Key messages immunomodulators for slides for Moncef meeting tomorrow 5/30
Attachments: ACTIV Therapeutics_053020v1.pptx

Hi Francis,

I have pre-emptively modified slide 7 to fit the description below. Please let me know if this makes more sense.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] | Mobile: [b6]

From: Adam, Stacey (FNIH) [T]
Sent: Friday, May 29, 2020 9:13 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Gonzalez, Nina <ningonzalez@deloitte.com>
Cc: Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Elsaid, Olivia <oelsaid@deloitte.com>
Subject: RE: Key messages immunomodulators for slides for Moncef meeting tomorrow 5/30

Hi Francis,

Here is what I know specifically from conversations with the companies.

- We know that BMS has ongoing Investigator Initiated Studies (IISs) with Abatacept that are early Phase II. Data not public yet.
- We know that Janssen also has a few preliminary trials, which is why they were getting ready to launch a large Phase 2 RCT of their own before they signed on to ACTIV-1, when we approached them. They had taken their protocol all the way through FDA approval.
- The only one I am not sure of is Cenicriviroc. AbbVie/Allergan have hinted at an IIS, but I would need to confirm. This was one of the R&D Consortium molecules, so I think they had some data to get it on that list.

I could reach out to the companies to see if they will give us more details, but I don't know if we would have it be your meeting with Moncef.

We can soften the language to say 2 of the 3 have known existing or ongoing Phase II is COVID-19.

Please let me know if you'd like the slide modified.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] | Mobile: [b6]

From: Collins, Francis (NIH/OD) [E] [b6]

Sent: Friday, May 29, 2020 9:02 PM

To: Gonzalez, Nina <ningonzalez@deloitte.com>

Cc: Adam, Stacey (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Elsaid, Olivia <oelsaid@deloitte.com>

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Nina

Nina Gonzalez

Deloitte Consulting LLP

Tel/Direct: +1 202 748 6535

ningonzalez@deloitte.com | www.deloitte.com

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APAR0000001307

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Sent: Friday, May 29, 2020 5:59 PM
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Cc: Adam, Stacey (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Gonzalez, Nina <ningonzalez@deloitte.com>; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

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David Wholley
 Senior Vice-President, Research Partnerships
 Foundation for the National Institutes of Health

b6

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/30/2020 1:23:02 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Elsaid, Olivia [oelsaid@deloitte.com]
Subject: RE: Key messages immunomodulators for slides for Moncef meeting tomorrow 5/30

Hi Francis,

That is my understanding that they were in hospitalized moderately ill.

Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: [b6] | Mobile: [b6]

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Friday, May 29, 2020 9:21 PM
To: Adam, Stacey (FNIH) [T] [b6]; Gonzalez, Nina <ningonzalez@deloitte.com>
Cc: Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Elsaid, Olivia <oelsaid@deloitte.com>
Subject: RE: Key messages immunomodulators for slides for Moncef meeting tomorrow 5/30

Thanks, Stacey. I assume these Phase II trials were for hospitalized COVID-19 patients, right?

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Friday, May 29, 2020 9:13 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Gonzalez, Nina <ningonzalez@deloitte.com>
Cc: Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Elsaid, Olivia <oelsaid@deloitte.com>
Subject: RE: Key messages immunomodulators for slides for Moncef meeting tomorrow 5/30

Hi Francis,

Here is what I know specifically from conversations with the companies.

- We know that BMS has ongoing Investigator Initiated Studies (IISs) with Abatacept that are early Phase II. Data not public yet.
- We know that Janssen also has a few preliminary trials, which is why they were getting ready to launch a large Phase 2 RCT of their own before they signed on to ACTIV-1, when we approached them. They had taken their protocol all the way through FDA approval.

- The only one I am not sure of is Cenicriviroc. AbbVie/Allergan have hinted at an IIS, but I would need to confirm. This was one of the R&D Consortium molecules, so I think they had some data to get it on that list.

I could reach out to the companies to see if they will give us more details, but I don't know if we would have it be your meeting with Moncef.

We can soften the language to say 2 of the 3 have known existing or ongoing Phase II is COVID-19.

Please let me know if you'd like the slide modified.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

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Hi all,

Thanks, this is an excellent set, though to keep the discussions with Moncef concise, I've moved some of the slides to the Appendix. See current version. I will send this to Janet now too.

One question: when the immunomodulator slide 7 says this:

All 3 agents have initial Phase II data or are currently running company-sponsored Phase II trials

What does that mean? Phase II trials for what application?

Francis

From: Gonzalez, Nina <ningonzalez@deloitte.com>

Sent: Friday, May 29, 2020 8:37 PM

To: Collins, Francis (NIH/OD) [E] [b6]

Cc: Adam, Stacey (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Elsaid, Olivia <oelsaid@deloitte.com>

Subject: RE: Key messages immunomodulators for slides for Moncef meeting tomorrow 5/30

Hi Francis,

See attached the latest version of the slides for the meeting tomorrow.

We'll be on standby for any edits you may have.

Thank you,

Nina

Nina Gonzalez

Deloitte Consulting LLP

Tel/Direct: +1 202 748 6535

ningonzalez@deloitte.com | www.deloitte.com

Please consider the environment before printing.

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Subject: [EXT] RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Hoping these are coming to me soon, as I may want to do some editing -- and then I wanted to run them past Janet tonight.

FC

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To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Adam, Stacey (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Gonzalez, Nina <ningonzalez@deloitte.com>; Parker, Ashley (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]
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Sent: 5/30/2020 1:44:13 AM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [b6]; Eisner, Mark [b6]; Gottesdiener, Keith [b6]; Hughes, Eric [b6]; Judy Carrier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [elkim@deloitte.com]; LaVange, Lisa [b6]; Levy, Elliot [b6]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaafe06ebd70-parkeras]; Patel, Naimish [b6]; Peppercorn, Amanda [b6]; Poole, Mike [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Amanda Peppercorn [b6]; Garner, Carl [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Burgess, Timothy [b6]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-roosenbey]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [b6]; Jansen, Kathrin [b6]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [b6]; Biggs, Mary [b6]; Butcher, Tina [b6]; Demarcus [b6]; Macone, Erin [b6]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan [jwachtel@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Alvarez, Rosa [rosalvarez@deloitte.com]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Anderson, Margaret [marganderson@deloitte.com]; Lucas Smalldon [b6]; Stratton, Benjamin [bstratton@DELOITTE.com]; Mollica, Linda /US [Linda.Mollica@sanofi.com]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Mensah, George (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]

Subject: Follow-up from ACTIV TX-Clinical Working Group Meeting #8

Attachments: Routine_Venous_Thromboembolism_Prophylaxis_May_Be.95638.pdf;
Coagulopathy_of_Coronavirus_Disease_2019.95637.pdf; 2020-05-28_TX-Clinical_WG_Meeting_Summary.pdf

Dear ACTIV TX-Clinical WG,

Thank you for another good discussion at our meeting yesterday. We'd like to thank our NHLBI colleagues who presented on their anticoagulation trial plans. I also appreciate all the feedback provided to the Agent Prioritization – mAb Sub team and on the RFI Survey Tool, which I will distribute to this group when live.

Please find attached the formal summary from the meeting. In addition, please find a couple of papers that Tim was kind enough to share with the group around anticoagulation treatment on the front lines of COVID-19.

The first is a reasonable primer for people who are not treating COVID patients with anticoagulation therapies. The authors are from the expert panel that presented to BARDA about 3.5 weeks ago that some of this group attended. https://journals.lww.com/ccmjournal/Abstract/9000/Coagulopathy_of_Coronavirus_Disease_2019.95637.aspx

Also another paper that endeavors to estimate the failure of 'routine' VTE prophylaxis for COVID treatment.

https://journals.lww.com/ccmjournal/Abstract/9000/Routine_Venous_Thromboembolism_Prophylaxis_May_Be.95638.aspx

Thanks,

Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct:

b6

Mobile:

b6

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/30/2020 2:39:33 AM
To: Jim Neaton [b6]; Jens Lundgren [b6]; Eric Hughes [b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Karen Lynn Price [b6]; LaVange, Lisa M [b6]; Sandeep Menon [b6]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Miller, Marissa A (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afea8bcd1c054bcd9250da63e1dbe947-millerma2]; Rachel Harrigan [b6]; William Erhardt [b6]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; [b6]
[b6]
[b6] Eron, Joe [b6]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; LHosey@s-3.com; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]
CC: Demarcus [b6]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jhoanna Roa [b6]; Eron, Joseph J Jr [b6]; Smith, David [b6]; Paul Klekotka [b6]; Ajay Nirula [b6]; Chen, Helen Q. [qingchen@deloitte.com]
Subject: Joint ACTIV-2 and ACTIV-3 Writing Team Meeting
Location: [b6]
Start: 6/4/2020 4:00:00 PM
End: 6/4/2020 5:00:00 PM
Show Time As: Tentative

Required Attendees: Jim Neaton; Jens Lundgren; Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Kozak, Marina (OS/ASPR/BARDA); Patterson, Amy (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Judy Currier; Karen Lynn Price; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Miller, Marissa A (NIH/NHLBI) [E]; Rachel Harrigan; William Erhardt; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); [b6]
[b6] Javan, Arzhang (NIH/NIAID) [E]; Roa, Jhoanna; [b6]; Kim, Peter (NIH/NIAID) [E]
Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Jhoanna Roa; Eron, Joseph J Jr; Smith, David; Paul Klekotka; Ajay Nirula; Chen, Helen Q.

Stacey Adam is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting

[b6]

Meeting ID: [b6]

Password: [b6]

One tap mobile

[b6] US (New York)
US (Germantown)

Dial by your location

[b6] US (New York)
US (Germantown)
US (Chicago)
US (San Jose)
US (Tacoma)
US (Houston)
US (San Jose)

Meeting ID: [b6]

Password: [b6]

Find your local number: [b6]

From: Mascola, John (NIH/VRC) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F78B40A596B4CA4A2850A429D1AE3F2-JMASCOLA]
Sent: 5/14/2020 1:02:32 PM
To: Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]
CC: Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: ChAdOx1
Flag: Follow up

Francis - we did make good progress on ACTIV Vaccine WG. Yesterday on the vaccine clinical trials subgroup, we presented the harmonized protocol approach and high level details of phase 3 design. There was good input on both and general agreement, with some useful recommendations on efficient ways to conduct phase 3.

One issues is

b4,b5

b4,b5

John

From: Marks, Peter [b6]
Sent: Thursday, May 14, 2020 6:23 AM
To: Collins, Francis (NIH/OD) [E] [b6] Mascola, John (NIH/VRC) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]
Cc: Fauci, Anthony (NIH/NIAID) [E] [b6] Wholley, David (FNIH) [T] [b6] Tabak, Lawrence (NIH/OD) [E] [b6] Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: ChAdOx1

Dear Francis,

We had made good progress with the Oxford AZ team on the clinical end before the contracting period began. From my last conversation with the AZ clinical team they were on board with the USG concept of a large phase 3 trial, potentially as part of a master protocol if the timing was right. Their major issue was getting moving rapidly.

Among other things, Tony, John and I discussed the concept that in addition to harmonized protocols we would consider merging the first two vaccines that are currently aiming to start phase 3 into one master protocol if they appeared to be staying on schedule for a July 1 start. Planning on one DSMB for at least these two candidates therefore makes a lot of sense.

LTAB0000019047

Later today I will be speaking with John again about this merged concept. After giving it very careful consideration, though it certainly involves significant extra work in protocol development and logistic planning, I believe that we should be actively planning for the two contingencies simultaneously:

- 1) Moderna and Oxford AZ enter phase 3 at different times (more than 2 weeks apart), in which case we will go with harmonized protocols, non-overlapping sites, and a single DSMB, and
- 2) Moderna and Oxford AZ enter phase 3 simultaneously (less than 2 weeks apart), in which case we should plan on one master protocol making use of all available sites. There is much to recommend this option, such that it is worth the effort in planning even if circumstances preclude proceeding along this path: 1) it could reduce the overall size of the trials by 10,000; 2) could help drive enrollment since fewer people will receive placebo; and 3) it will produce comparative efficacy data.

On the manufacturing front

b4,b5

b4,b5

Best Regards,
Peter

From: Collins, Francis (NIH/OD) [E]

b6

Sent: Thursday, May 14, 2020 5:38 AM

To: Mascola, John R (NIH) ; Lane, Henry C (NIH) ; Marks, Peter

b6

Cc: Fauci, Anthony S (NIH) ; Wholley, David N (NIH) ; Tabak, Lawrence A (NIH) ; Parker, Ashley S (NIH)

b6

b6

b6

b6

Subject: ChAdOx1

Gentlemen:

I need to know the update on where we are with Oxford, A-Z, and ChAdOx1. I see there's a BARDA WebEx at 5 pm, and I have a rescheduled phone call this morning with John Bell. I'd like to be as useful as possible in making a plan that includes this vaccine program as part of the harmonized master protocol. Advice about how to use the call with John Bell most effectively would be most welcome!

And did the Vaccines WG make good progress yesterday on the details of the harmonized master protocol? Did they agree in principle to a single DSMB?

Thanks, Francis

From: Wolinetz, Carrie (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1C655040D47346C7B04D7BC11A403ECB-WOLINETZCD]
Sent: 5/14/2020 1:19:09 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
Subject: FW: ChAdOx1

Just jumping in briefly to say that Ashley has mentioned some disquiet to me – prior to this email – that the industry chair of this WG seemed conflicted. She said it felt like [REDACTED] b4,b5 [REDACTED] b4,b5 but since the NIH folks on the group didn't push back she wasn't sure if she was misreading things. She doesn't know the players involved and neither do I, so take that observation for whatever it's worth. But thought it was more interesting in light of this email from John.

From: Mascola, John (NIH/VRC) [E] [REDACTED] b6 [REDACTED]
Sent: Thursday, May 14, 2020 9:03 AM
To: Marks, Peter (FDA/CBER) [REDACTED] b6 [REDACTED] Collins, Francis (NIH/OD) [E] [REDACTED] b6 [REDACTED] Lane, Cliff (NIH/NIAID) [E] [REDACTED] b6 [REDACTED]
Cc: Fauci, Anthony (NIH/NIAID) [E] [REDACTED] b6 [REDACTED]; Wholley, David (FNIH) [T] [REDACTED] b6 [REDACTED]; Tabak, Lawrence (NIH/OD) [E] [REDACTED] b6 [REDACTED]; Parker, Ashley (NIH/OD) [E] [REDACTED] b6 [REDACTED]
Subject: RE: ChAdOx1

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One issues is [REDACTED] b4,b5 [REDACTED]
[REDACTED] b4,b5 [REDACTED]

John

From: Marks, Peter [REDACTED] b6 [REDACTED]
Sent: Thursday, May 14, 2020 6:23 AM
To: Collins, Francis (NIH/OD) [E] [REDACTED] b6 [REDACTED] Mascola, John (NIH/VRC) [E] [REDACTED] b6 [REDACTED] Lane, Cliff (NIH/NIAID) [E] [REDACTED] b6 [REDACTED]
Cc: Fauci, Anthony (NIH/NIAID) [E] [REDACTED] b6 [REDACTED]; Wholley, David (FNIH) [T] [REDACTED] b6 [REDACTED]; Tabak, Lawrence (NIH/OD) [E] [REDACTED] b6 [REDACTED]; Parker, Ashley (NIH/OD) [E] [REDACTED] b6 [REDACTED]
Subject: RE: ChAdOx1

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On the manufacturing front

b4,b5

b4,b5

Best Regards,
Peter

From: Collins, Francis (NIH/OD) [E]

b6

Sent: Thursday, May 14, 2020 5:38 AM

To: Mascola, John R (NIH)

b6

Lane, Henry C (NIH)

b6

Marks, Peter

b6

Cc: Fauci, Anthony S (NIH)

b6

; Wholley, David N (NIH)

b6

Tabak, Lawrence A

(NIH)

b6

; Parker, Ashley S (NIH)

b6

Subject: ChAdOx1

Gentlemen:

I need to know the update on where we are with Oxford, A-Z, and ChAdOx1. I see there's a BARDA WebEx at 5 pm, and I have a rescheduled phone call this morning with John Bell. I'd like to be as useful as possible in making a plan that includes this vaccine program as part of the harmonized master protocol. Advice about how to use the call with John Bell most effectively would be most welcome!

And did the Vaccines WG make good progress yesterday on the details of the harmonized master protocol? Did they agree in principle to a single DSMB?

Thanks, Francis

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 5/14/2020 2:45:11 PM
To: Marks, Peter [b6]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]
CC: Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: ChAdOx1

Yes, I'd be glad to join. We should start with Dolsten.

From: Marks, Peter [b6]
Sent: Thursday, May 14, 2020 9:05 AM
To: Mascola, John (NIH/VRC) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6] Lane, Cliff (NIH/NIAID) [E] [b6]
Cc: Fauci, Anthony (NIH/NIAID) [E] [b6] Wholley, David (FNIH) [T] [b6] Tabak, Lawrence (NIH/OD) [E] [b6] Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: ChAdOx1

Dear John,

Thanks for bringing the Pfizer issue up. I think that a call with their head of development and possibly also their CEO may be needed, and I wonder if Francis would like to join?

Best Regards,
Peter

From: Mascola, John (NIH/VRC) [E] [b6]
Sent: Thursday, May 14, 2020 9:03 AM
To: Marks, Peter [b6]; Collins, Francis S (NIH) [b6]; Lane, Henry C (NIH) [b6]
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One issues [b4,b5]

b4,b5

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Sent: Thursday, May 14, 2020 6:23 AM
To: Collins, Francis (NIH/OD) [E] [b6] Mascola, John (NIH/VRC) [E] [b6] Lane, Cliff (NIH/NIAID) [E] [b6]
Cc: Fauci, Anthony (NIH/NIAID) [E] [b6] Wholley, David (FNIH) [T] [b6] Tabak, Lawrence (NIH/OD) [E] [b6] Parker, Ashley (NIH/OD) [E] [b6]
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On the manufacturing front [b4,b5]

[b4,b5]

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Sent: Thursday, May 14, 2020 5:38 AM
To: Mascola, John R (NIH) [b6] Lane, Henry C (NIH) [b6] Marks, Peter [b6]
Cc: Fauci, Anthony S (NIH) [b6] Wholley, David N (NIH) [b6] Tabak, Lawrence A (NIH) [b6] Parker, Ashley S (NIH) [b6]
Subject: ChAdOx1

COLL0000010992

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Sent: 5/14/2020 2:52:17 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]
CC: Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]
Subject: RE: ChAdOx1

I don't sense that other companies have any major concerns. Merck, JJ, Sanofi – all part of good productive discussion. But Pfizer's two representatives spoke more than all the other companies combined for this particular hour call.

I'd ask Dough to give his perspective here.

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 10:32 AM
To: Mascola, John (NIH/VRC) [E] [b6]; Marks, Peter (FDA/CBER) [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]
Cc: Fauci, Anthony (NIH/NIAID) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Lowy, Douglas (NIH/NCI) [E] [b6]
Subject: RE: ChAdOx1

Thanks for this input, John and Peter.

It's too bad that Pfizer is dominating the discussion about the DSMB, when they apparently don't intend to take part in the harmonized master protocol anyway. Are there other companies represented on the Vaccines WG who might feel differently? I'm looping in Doug (and should have done so earlier, sorry!).

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Sent: Thursday, May 14, 2020 9:03 AM
To: Marks, Peter (FDA/CBER) [b6]; Collins, Francis (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]
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One issues

b4,b5

b4,b5

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b6

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To: Collins, Francis (NIH/OD) [E]

b6

Mascola, John (NIH/VRC) [E]

b6

Lane,

Cliff (NIH/NIAID) [E]

b6

Cc: Fauci, Anthony (NIH/NIAID) [E]

b6

Wholley, David (FNIH) [T]

b6

; Tabak,

Lawrence (NIH/OD) [E]

b6

Parker, Ashley (NIH/OD) [E]

b6

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On the manufacturing front

b4,b5

b4,b5

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APAR0000006218

From: Collins, Francis (NIH/OD) [E] [b6]

Sent: Thursday, May 14, 2020 5:38 AM

To: Mascola, John R (NIH) [b6]; Lane, Henry C (NIH) [b6]; Marks, Peter

[b6]

Cc: Fauci, Anthony S (NIH) [b6]; Wholley, David N (NIH) [b6]; Tabak, Lawrence A (NIH) [b6]; Parker, Ashley S (NIH) [b6]

Subject: ChAdOx1

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Thanks, Francis

From: Lowy, Douglas (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F1B7B8FE4739478BB17840C56902718A-LOWYD]
Sent: 5/14/2020 3:06:20 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]
CC: Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: Re: ChAdOx1

Francis: I don't know the perspective of the other companies. As Kathrin realizes, the regulatory perspective will be important. Doug

From: "Collins, Francis (NIH/OD) [E]" [b6]
Date: Thursday, May 14, 2020 at 10:32 AM
To: "Mascola, John (NIH/VRC) [E]" [b6], "Marks, Peter (FDA/CBER)" [b6], "Lane, Cliff (NIH/NIAID) [E]" [b6]
Cc: "Fauci, Anthony (NIH/NIAID) [E]" [b6], "Wholley, David (FNIH) [T]" [b6], "Tabak, Lawrence (NIH/OD) [E]" [b6], "Parker, Ashley (NIH/OD) [E]" [b6], "Lowy, Douglas (NIH/NCI) [E]" [b6]
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Cc: Fauci, Anthony (NIH/NIAID) [E] [b6], Wholley, David (FNIH) [T] [b6], Tabak, Lawrence (NIH/OD) [E] [b6], Parker, Ashley (NIH/OD) [E] [b6]
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b4,b5

b4,b5

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On the manufacturing front

b4,b5

b4,b5

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Peter

APAR0000006221

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Sent: Thursday, May 14, 2020 5:38 AM

To: Mascola, John R (NIH) [b6]; Lane, Henry C (NIH) [b6]; Marks, Peter

[b6]

Cc: Fauci, Anthony S (NIH) [b6]; Wholley, David N (NIH) [b6]; Tabak, Lawrence A (NIH) [b6]; Parker, Ashley S (NIH) [b6]

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 5/14/2020 5:23:45 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: RE: ChAdOx1

Flag: Follow up

We can talk about in the wr

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 1:23 PM
To: Wholley, David (FNIH) [T] [b6]
Subject: RE: ChAdOx1

Running flat out, can we discuss at the 2:30 War Room? Or needs a private call?

From: Wholley, David (FNIH) [T] [b6]
Sent: Thursday, May 14, 2020 12:05 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: FW: ChAdOx1

Do you have a minute to chat about this directly, Francis?

From: Marks, Peter [b6]
Sent: Thursday, May 14, 2020 9:05 AM
To: Mascola, John (NIH/VRC) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]
Cc: Fauci, Anthony (NIH/NIAID) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
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b6

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b6

; Wholley, David (FNIH) [T]

b6

Tabak,

Lawrence (NIH/OD) [E]

b6

; Parker, Ashley (NIH/OD) [E]

b6

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b4,b5

b4,b5

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COLL0000021841

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To: Mascola, John R (NIH) [b6]; Lane, Henry C (NIH) [b6]; Marks, Peter [b6]

Cc: Fauci, Anthony S (NIH) [b6]; Wholley, David N (NIH) [b6]; Tabak, Lawrence A (NIH) [b6]; Parker, Ashley S (NIH) [b6]

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From: Marks, Peter [b6]
Sent: 5/17/2020 12:04:58 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: ChAdOx1

Dear Francis,

b4,b5

b4,b5

Best Regards,
Peter

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Saturday, May 16, 2020 8:00 PM
To: Marks, Peter [b6]; Fauci, Anthony S (NIH) [b6]; Mascola, John R (NIH) [b6]; Lane, Henry C (NIH) [b6]
Cc: Wholley, David N (NIH) [b6]; Tabak, Lawrence A (NIH) [b6]; Parker, Ashley S (NIH) [b6]
Subject: RE: ChAdOx1

Just a brief word of concern – [b4,b5]

b4,b5

From: Marks, Peter [b6]
Sent: Saturday, May 16, 2020 3:13 PM
To: Fauci, Anthony (NIH/NIAID) [E] [b6]; Mascola, John (NIH/VRC) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]
Cc: Wholley, David (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: ChAdOx1

Dear Tony,

Will certainly include you next week on this call.

APAR0000006209

Best Regards,
Peter

From: Fauci, Anthony (NIH/NIAID) [E] <[b6]>
Sent: Thursday, May 14, 2020 9:12 AM
To: Marks, Peter <[b6]>; Mascola, John R (NIH) <[b6]>; Collins, Francis S (NIH) <[b6]>; Lane, Henry C (NIH) <[b6]>
Cc: Wholley, David N (NIH) <[b6]>; Tabak, Lawrence A (NIH) <[b6]>; Parker, Ashley S (NIH) <[b6]>
Subject: RE: ChAdOx1

I would also like to be on that call with the Pfizer CEO if we could possible arrange it.

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases
Building 31, Room 7A-03
31 Center Drive, MSC 2520
National Institutes of Health
Bethesda, MD 20892-2520
Phone: [b6]
FAX: (301) 496-4409
E-mail: [b6]

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From: Marks, Peter <[b6]>
Sent: Thursday, May 14, 2020 9:05 AM
To: Mascola, John (NIH/VRC) [E] <[b6]>; Collins, Francis (NIH/OD) [E] <[b6]>; Lane, Cliff (NIH/NIAID) [E] <[b6]>
Cc: Fauci, Anthony (NIH/NIAID) [E] <[b6]>; Wholley, David (FNIH) [T] <[b6]>; Tabak, Lawrence (NIH/OD) [E] <[b6]>; Parker, Ashley (NIH/OD) [E] <[b6]>
Subject: RE: ChAdOx1

Dear John,

Thanks for bringing the Pfizer issue up. I think that a call with their head of development and possibly also their CEO may be needed, and I wonder if Francis would like to join?

Best Regards,
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From: Mascola, John (NIH/VRC) [E] <[b6]>
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To: Marks, Peter <[b6]>; Collins, Francis S (NIH) <[b6]>; Lane, Henry C (NIH) <[b6]>
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(NIH) [b6] Parker, Ashley S (NIH) [b6]

Subject: RE: ChAdOx1

Francis - we did make good progress on ACTIV Vaccine WG. Yesterday on the vaccine clinical trials subgroup, we presented the harmonized protocol approach and high level details of phase 3 design. There was good input on both and general agreement, with some useful recommendations on efficient ways to conduct phase 3.

One issues [b4,b5]

b4,b5

John

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Sent: Thursday, May 14, 2020 6:23 AM

To: Collins, Francis (NIH/OD) [E] [b6]; Mascola, John (NIH/VRC) [E] [b6] Lane, Cliff (NIH/NIAID) [E] [b6]

Cc: Fauci, Anthony (NIH/NIAID) [E] [b6]; Wholley, David (FNIH) [T] [b6] Tabak, Lawrence (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]

Subject: RE: ChAdOx1

Dear Francis,

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Later today I will be speaking with John again about this merged concept. After giving it very careful consideration, though it certainly involves significant extra work in protocol development and logistic planning, I believe that we should be actively planning for the two contingencies simultaneously:

- 1) Moderna and Oxford AZ enter phase 3 at different times (more than 2 weeks apart), in which case we will go with harmonized protocols, non-overlapping sites, and a single DSMB, and
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On the manufacturing front [b4,b5]

b4,b5

Best Regards,
Peter

From: Collins, Francis (NIH/OD) [E] [b6]

Sent: Thursday, May 14, 2020 5:38 AM

To: Mascola, John R (NIH) [b6]; Lane, Henry C (NIH) [b6]; Marks, Peter [b6]

Cc: Fauci, Anthony S (NIH) [b6]; Wholley, David N (NIH) [b6]; Tabak, Lawrence A (NIH) [b6]; Parker, Ashley S (NIH) [b6]

Subject: ChAdOx1

Gentlemen:

I need to know the update on where we are with Oxford, A-Z, and ChAdOx1. I see there's a BARDA WebEx at 5 pm, and I have a rescheduled phone call this morning with John Bell. I'd like to be as useful as possible in making a plan that includes this vaccine program as part of the harmonized master protocol. Advice about how to use the call with John Bell most effectively would be most welcome!

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Thanks, Francis

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Sent: 5/17/2020 7:09:19 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: ChAdOx1

I'm speaking to Dolsten at 6:30 PM this evening – following up an email that seemed to suggest he wanted to talk. I'll let everybody know what happens then.

From: Wholley, David (FNIH) [T] [b6]
Sent: Sunday, May 17, 2020 2:16 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: RE: ChAdOx1

Thanks – sorry , sent my other note before I saw this one.

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Saturday, May 16, 2020 8:00 PM
To: Marks, Peter (FDA/CBER) [b6]; Fauci, Anthony (NIH/NIAID) [E] [b6]
Mascola, John (NIH/VRC) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]
Cc: Wholley, David (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: ChAdOx1

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b4,b5

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COLL0000020325

(NIH) [b6]

Subject: RE: ChAdOx1

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Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases
Building 31, Room 7A-03
31 Center Drive, MSC 2520
National Institutes of Health
Bethesda, MD 20892-2520
Phone: [b6]
FAX: (301) 496-4409
E-mail: [b6]

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[b4,b5]

COLL0000020325

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COLL0000020325

(NIH) [b6]; Parker, Ashley S (NIH) [b6]

Subject: ChAdOx1

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Thanks, Francis

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 5/13/2020 9:22:41 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: RE: Woodcock summary of current trials

Yes

From: Wholley, David (FNIH) [T] [b6]
Sent: Tuesday, May 12, 2020 10:08 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Austin, Christopher (NIH/NCATS) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]
Anderson, James (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Freire, Maria (FNIH) [T] [b6]
Subject: RE: Woodcock summary of current trials

So I can send to the ACTIV Working Group Co-chairs, yes?

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Tuesday, May 12, 2020 9:43 PM
To: Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]
Subject: Woodcock summary of current trials

Interesting inventory from Janet...

From: Woodcock, Janet [b6]
Sent: Tuesday, May 12, 2020 9:38 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

Yes you can share. It's a bit out of date. As I said I'm doing a deeper dive on convalescent plasma and the neutralizing MoAbs. Should have soon. Need to fill in detail of all planned DOD and NIH studies. Should get to that this week. JW

From: Collins, Francis (NIH/OD) [E] [b6]

Date: May 12, 2020 at 8:48:22 PM EDT

To: Woodcock, Janet [b6]

Subject: RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

Hi Janet,

I just got to this e-mail (it's been that kind of day). Wow, there is a LOT of useful information here. May I share with ACTIV leadership?

Francis

From: Woodcock, Janet [b6]

Sent: Tuesday, May 12, 2020 5:01 PM

To: Collins, Francis (NIH/OD) [E] [b6]

Subject: FW: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

From: Collins, Francis (NIH/OD) [E] [b6]

Sent: Tuesday, May 12, 2020 1:31 PM

To: Woodcock, Janet [b6]

Subject: RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

5 pm? [b6] if you can. Otherwise after 7 pm is good

From: Woodcock, Janet [b6]

Sent: Tuesday, May 12, 2020 1:08 PM

To: Collins, Francis (NIH/OD) [E] [b6]

Subject: RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

No have to brief higher ups. Later better. Jwv

From: Collins, Francis (NIH/OD) [E] [b6]

Date: May 12, 2020 at 12:49:32 PM EDT

To: Woodcock, Janet [b6]

Subject: RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

Yes, I would like that. Can you do 3:30?

From: Woodcock, Janet [b6]

Sent: Tuesday, May 12, 2020 11:28 AM

To: Collins, Francis (NIH/OD) [E] [b6]

Subject: FW: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

Can we discuss before tomorrow? jw

From: Wholley, David (FNIH) [T] [b6]

Sent: Tuesday, May 12, 2020 10:46 AM

To: Collins, Francis S (NIH) [b6] Stoffels, Paul [JJCUS] [b6]; Fauci, Anthony S (NIH)

b6 Gibbons, Gary H (NIH) b6 Woodcock, Janet
b6 Pao, William b6 ; Dolsten, Mikael
Cc: Colvis, Christine M (NIH) b6 Desrosiers, Betsy b6 Hughes,
Eric b6 Read, Sarah W (NIH) b6 Jansen, Kathrin
b6 Kurilla, Michael G (NIH) b6 ; Lowy, Douglas R (NIH)
b6 ; Young, John b6 Freire, Maria C (NIH) b6 Tabak,
Lawrence A (NIH) b6 Lane, Henry C (NIH) b6 ; Parker, Ashley S (NIH)
b6 ; Anderson, James M (NIH) b6 ; Austin, Christopher P (NIH)
b6 Wolinetz, Carrie D (NIH) b6

Subject: FW: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

Dear ACTIV Executive Committee Members:

Please see the attached letter from the ACTIV Therapeutics-Clinical Working Group received this morning, for consideration on tomorrow morning's Executive Committee teleconference. While we expect the proposals contained herein will be one major topic of discussion, the purpose of the meeting is to hear from all of the Working Group co-chairs (copied on this note) regarding what is working and where they may be facing challenges in ACTIV, and jointly discuss strategy moving forward.

David

From: Adam, Stacey (FNIH) [T] b6
Sent: Tuesday, May 12, 2020 9:52 AM
To: Wholley, David (FNIH) [T] b6
Cc: Read, Sarah (NIH/NIAID) [E] b6 ; Eric Hughes b6 Carlos O Garner
b6 ; Judy Currier b6 Keith Gottesdiener
b6 ; Amanda Peppercorn b6 Stein, Peter (FDA/CDER)
b6 Higgs, Elizabeth (NIH/NIAID) [E] b6 elkim@deloitte.com
Subject: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

Hi David,

Please find attached a letter from the Therapeutics-Clinical Working Group to the ACTIV Executive Committee for their consideration. Overall, the letter is meant to relate some broad challenges and issues that the Therapeutics-Clinical group thinks the ACTIV PPP is facing, as well as some very specific requests for assistance from the ACTIV EC for our team.

Please relay this to the ACTIV EC for their review. Our group would welcome any feedback they have.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health
Direct: b6 | Mobile: b6
fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic

APAR0000005422-2441716



From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 5/15/2020 1:24:33 AM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: FW: Woodcock summary of current trials
Attachments: jwnationalCOVID19therapeutics.pptx

You asked me earlier about the list of 21 mAb companies Janet was referring to. See slide 8 from this deck FC distributed Tuesday, think that is it.

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Tuesday, May 12, 2020 9:43 PM
To: Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6] Austin, Christopher (NIH/NCATS) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]
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To: Collins, Francis (NIH/OD) [E] [b6]
Subject: RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

No have to brief higher ups. Later better. Jwv

From: Collins, Francis (NIH/OD) [E] [b6]
Date: May 12, 2020 at 12:49:32 PM EDT
To: Woodcock, Janet [b6]
Subject: RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

Yes, I would like that. Can you do 3:30?

From: Woodcock, Janet [b6]
Sent: Tuesday, May 12, 2020 11:28 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: FW: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

Can we discuss before tomorrow? jw

From: Wholley, David (FNIH) [T] [b6]
Sent: Tuesday, May 12, 2020 10:46 AM
To: Collins, Francis S (NIH) [b6]; Stoffels, Paul [JJCUS] [b6]; Fauci, Anthony S (NIH) [b6]; Gibbons, Gary H (NIH) [b6]; Woodcock, Janet [b6]; Pao, William [b6]; Dolsten, Mikael [b6]
Cc: Colvis, Christine M (NIH) [b6]; Desrosiers, Betsy [b6]; Hughes, Eric [b6]; Read, Sarah W (NIH) [b6]; Jansen, Kathrin [b6]; Kurilla, Michael G (NIH) [b6]; Lowy, Douglas R (NIH) [b6]; Young, John [b6]; Freire, Maria C (NIH) [b6]; Tabak, Lawrence A (NIH) [b6]; Lane, Henry C (NIH) [b6]; Parker, Ashley S (NIH) [b6]; Anderson, James M (NIH) [b6]; Austin, Christopher P (NIH) [b6]; Wolinetz, Carrie D (NIH) [b6]
Subject: FW: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

Dear ACTIV Executive Committee Members:

Please see the attached letter from the ACTIV Therapeutics-Clinical Working Group received this morning, for consideration on tomorrow morning's Executive Committee teleconference. While we expect the proposals contained herein will be one major topic of discussion, the purpose of the meeting is to hear from all of the Working Group co-chairs (copied on this note) regarding what is working and where they may be facing challenges in ACTIV, and jointly discuss strategy moving forward.

David

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Tuesday, May 12, 2020 9:52 AM
To: Wholley, David (FNIH) [T] [b6]
Cc: Read, Sarah (NIH/NIAID) [E] [b6]; Eric Hughes [b6]; Carlos O Garner [b6]; Judy Currier [b6]; Keith Gottesdiener [b6]; Amanda Peppercorn [b6]; Stein, Peter (FDA/CDER) [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6] [elkim@deloitte.com]
Subject: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

Hi David,

Please find attached a letter from the Therapeutics-Clinical Working Group to the ACTIV Executive Committee for their consideration. Overall, the letter is meant to relate some broad challenges and issues that the Therapeutics-Clinical group thinks the ACTIV PPP is facing, as well as some very specific requests for assistance from the ACTIV EC for our team.

Please relay this to the ACTIV EC for their review. Our group would welcome any feedback they have.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health
Direct: [b6] | Mobile: [b6]
fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/15/2020 1:38:44 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Woodcock summary of current trials

Ah! Thanks! It would've been nice to include this slide in our set for Moncef but it's too premature.

I'm sending you slides shortly.

Thanks,
Ashley

From: Wholley, David (FNIH) [T] [b6]
Sent: Thursday, May 14, 2020 9:25 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: Woodcock summary of current trials

You asked me earlier about the list of 21 mAb companies Janet was referring to. See slide 8 from this deck FC distributed Tuesday, think that is it.

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Tuesday, May 12, 2020 9:43 PM
To: Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]
Subject: Woodcock summary of current trials

Interesting inventory from Janet...

From: Woodcock, Janet [b6]
Sent: Tuesday, May 12, 2020 9:38 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

Yes you can share. It's a bit out of date. As I said I'm doing a deeper dive on convalescent plasma and the neutralizing MoAbs. Should have soon. Need to fill in detail of all planned DOD and NIH studies. Should get to that this week. Jw

From: Collins, Francis (NIH/OD) [E] [b6]
Date: May 12, 2020 at 8:48:22 PM EDT
To: Woodcock, Janet [b6]
Subject: RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

Hi Janet,

I just got to this e-mail (it's been that kind of day). Wow, there is a LOT of useful information here. May I share with ACTIV leadership?

Francis

From: Woodcock, Janet [b6]
Sent: Tuesday, May 12, 2020 5:01 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: FW: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Tuesday, May 12, 2020 1:31 PM
To: Woodcock, Janet [b6]
Subject: RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

5 pm? [b6] if you can. Otherwise after 7 pm is good

From: Woodcock, Janet [b6]
Sent: Tuesday, May 12, 2020 1:08 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

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Lawrence A (NIH) [b6]; Lane, Henry C (NIH) [b6] Parker, Ashley S (NIH)
[b6]; Anderson, James M (NIH) [b6] Austin, Christopher P (NIH)
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[b6]; Amanda Peppercorn [b6]; Stein, Peter (FDA/CDER)
[b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6]; elkim@deloitte.com
Subject: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

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Director, Cancer
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